EPA Registration No. 11556-131 Vol. 1

Mr. F. Terry McNamara
Bayer Health Care LLC
P.O. Box 390
Shawnee Mission, KS 66201

MAR 30 2004

Dear Mr. McNamara:

Subject: Amendment - alternate formulation
CyLence Ultra Cattle Insecticide Ear Tag
EPA Registration No. 11556-131
Your Submission Dated January 27, 2004

Your Confidential Statement of Formula (CSF)dated January 27, 2004 has been reviewed and is not acceptable for the following reasons:

a. The amount of the sources of active ingredient (EPA Registration Number [redacted] needs to be adjusted to meet the label claim of 20.0% of Piperonyl Butoxide since the purity of Piperonyl Butoxide is not [redacted] it will not meet the label claim of 20.0%.

b. You must either exclude EPA Registration Number [redacted] from the CSF or increase the amount of Piperonyl Butoxide to [redacted] in the basic formulation in order to meet the label claim of 20.0%.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505)

Enclosure

03/24/04

DATE DP BARCODE No.: D298850 **EPA REG. NO.:** 11556-131
PRODUCT NAME: CYLENCE ULTRA CATTLE INSECTICIDE EAR TAG
PC Codes 128831, 067501
Decision No. 338773
FOOD USE [ ]
COMPANY: BAYER HEALTH CARE LLC

FROM: Indira Gairola, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505C)

TO: George Larocca / Linda Deluise PM 13
Insecticide Branch/RD(7505C)

INTRODUCTION:

BAYER HEALTH CARE LLC has submitted amended basic formulation CSF dated 01/27/04 for the subject product CYLENCE ULTRA CATTLE INSECTICIDE EAR TAG. The sources of active ingredients are registered [redacted]

SUMMARY OF FINDINGS:

The submitted Basic CSF dated 01/27/04 for the subject product CYLENCE ULTRA CATTLE INSECTICIDE EAR TAG was reviewed and details will be discussed as follows :

1. The basic CSF dated 01/27/04 for the subject product agrees with the label claim of 8.0 % of the active ingredient Beta Cyfluralin and 20.0% of Piperonyl Butoxide .

2. All of the inerts are cleared for the proposed use.

3. Applicant is making amendment to the Confidential Statement of Formula by adding alternate sources of Piperonyl Butoxide.

4. Amount in one of the sources of active ingredients [redacted] needs to be adjusted to meet the label claim of 20.0% of Piperonyl Butoxide since the purity of Piperonyl Butoxide is not [redacted] it will not meet the label claim of 20.0%.

5. Applicant must either exclude [redacted] from CSF or increase the amount of Piperonyl Butoxide to [redacted] in the basic formulation in order to meet the label claim of 20.0%.

6. The basic CSF dated 1 01/27/04 for the subject product is will be accepted subject to the aforementioned change.

CONCLUSIONS:

TRB has reviewed the submitted basic CSF dated 01/27/04 for the above mentioned subject product and has concluded that:

1. The basic CSF dated 01/27/04 for the subject product is will be accepted subject to the aforementioned change. See findings 4, 5 and 6.

via Federal Express – Express Saver – 01/27/04

Document Processing Desk (AMEND)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Enclosure: Application for Pesticide Amendment –
CyLence Ultra Cattle Insecticide Ear Tag
(EPA Reg. No. 11556-131) – with two copies CSF

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
11556-131	George LaRocca	☐ None ☐ Restricted
4. Company/Product (Name) CyLence Ultra Cattle Insecticide Ear Tag	PM#	

5. Name and Address of Applicant *(Include ZIP Code)*

Bayer HealthCare LLC, Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

● ☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in reponse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional pege(s) if necessary. (For section I and Section II.)

The attached CSF has been revised to include an additional alternate source for the active ingredient Piperonyl Butoxide.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packeging	Water Soluble Packaging	2. Type of Container
☐ Yes ● ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Reteil Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Label accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
F. Terry McNamara	Director, Preclinical Dev & Regulatory Affairs	(913) 268-2588

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

8. Date Application Received (Stamped)

2. Signature	3. Title
F. Terry McNamara	Director, Preclinical Development & Regulatory Affairs
4. Typed Name F. Terry McNamara	**5. Date** January 27, 2004

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Pages 7-10 - *Confidential Statements of Formula may be entitled to confidential treatment*

Reason to Issue: Add Allflex applicator statement, and revise company name.

Date: 05/28/03
Supersedes: 03/12/02

Pouch

CYLENCE® ULTRA

INSECTICIDE CATTLE EAR TAG

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks for Up to Five Months.

		Percent By Weight
Active Ingredients	Beta-cyfluthrin; Cyano (4-fluoro-3-phenyoxyphenyl) methyl 3-(2,2 – dichloroethenyl) 2, 2 – dimethylcyclopropane carboxylate	8%
	Piperonyl butoxide	20%
Other Ingredients	. . . . .	72%
Total	. . . . .	100%

Keep Out of Reach of Children

CAUTION

See Box For Precautionary Statements

ACCEPTED
JUN 26 2003
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 11556-131

Net Contents: 10 Tags - 0.5 oz per tag

Manufactured for
Bayer HealthCare, Animal Health Division
Shawnee Mission, KS 66201 U.S.A.

EPA Est. No.
EPA Reg. No. 11556-131

Box (Front)

CYLENCE® ULTRA

INSECTICIDE CATTLE EAR TAG

For Use with Allflex Global Applicator with red pin and white clip.

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks

- Effective Against Face Flies and Pyrethroid Susceptible Horn Flies for up to 5 months.
- Kills and Repels Face Flies – mechanical vector of *Moraxella bovis* bacteria causing "pink eye" of cattle
- Synergized for extra performance

		Percent By Weight
Active Ingredients	Beta-cyfluthrin; Cyano (4-fluoro-3-phenyoxyphenyl) methyl 3-(2,2 – dichloroethenyl) 2, 2 – dimethylcyclopropane carboxylate	8%
	Piperonyl Butoxide Technical	20%
Other Ingredients	. . . . .	72%
Total	. . . . .	100%

Keep Out of Reach of Children

CAUTION

See Side Panel for Additional Precautionary Statements

Net Contents: 2 pouches of 10 tags each – 0.5 oz per tag

Bayer HealthCare, Animal Health Division
Shawnee Mission, KS 66201 U.S.A.

Box (Side Panel)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

May cause eye irritation. Harmful if swallowed, inhaled or absorbed through the skin. Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wear nonpermeable protective gloves when applying or removing tags. Wash thoroughly with soap and water after use and before eating, drinking or using tobacco.

FIRST AID

If in Eyes:
- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present after the first 5 minutes, and then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If Swallowed:
- Call a poison control center or doctor immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin or clothing:
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If Inhaled:
- Move person to fresh air.
- If person is not breathing call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the product information center at 1-800-255-6826, or for emergency medical treatment information call 1-877-258-2280.

Environmental Hazards: This pesticide is toxic to fish. Do not contaminate water when disposing of used tags. Apply this product only as specified on the label.

Directions for Use:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in the possession of the user at the time of pesticide application.

For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and dairy cattle (including lactating).

All mature animals in the herd should be tagged. For adequate control of horn flies attach one tag per animal. For optimum control of face flies, horn flies, gulf coast ticks, and spinose ear ticks, attach one tag to each ear (two per animal). Replace as necessary. CyLence® Ultra Insecticide Ear Tags have been proven to be effective against face and horn flies for up to five months.

Use the Allflex Global Applicator with the red pin and white clip to apply tags to cattle.

Apply as indicated (Figures 1-4). Calves less than 3 months of age should not be tagged as ear damage may result. Remove tags at end of fly season or prior to slaughter.

(Illustration)	(Illustration)	(Illustration)	(Illustration)
Figure 1	**Figure 2**	**Figure 3**	**Figure 4**
Disinfect pliers prior to use. Place male button onto pin until it projects through the tip.	Slide tag under the clip of the pliers by depressing the lever.	Position tag in the center portion of the front side of the ear.	Apply the tag between the second and third rib cartilage.

Continual exposure of horn flies to a single class of insecticide (e.g. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance it is important to rotate the class of insecticide used and/or the method of horn fly control on a seasonal basis. CyLence® Ultra Cattle Ear Tag contains the pyrethroid insecticide beta cyfluthrin plus piperonyl butoxide, which is an insecticide synergist.

Reason to Issue:	Add Allflex applicator statement, and revise company name.	Date:	05/28/03
		Supersedes:	03/12/02
		Page 5 of 6	

Box (Back)

Storage and Disposal:

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in cool place in original container. Opened pouches containing ear tags should be resealed for storage.

Pesticide Disposal: Waste (spent tags) resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Dispose of empty pouch in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned stay out of smoke.

EPA Est. No.
EPA Reg. No. 11556-131

Reason to Issue:	Add Allflex applicator statement, and revise company name.	Date:	05/28/03
		Supersedes:	03/12/02
		Page 6 of 6	

Box (Side Panel)

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division, warrants that this material conforms to the chemical description on the label. BAYER HEALTHCARE MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, and no agent of Bayer HealthCare, is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 4, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

TERRY MCNAMARA
BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION
PO Box 390
SHAWNEE MISSION, KS 66201-0390

PRODUCT NAME: CUTTER ULTRA INSECTICIDE CATTLE EAR TAG
COMPANY NAME: BAYER HEALTHCARE LLC
EPA FILE SYMBOL: 11556-131
EPA RECEIPT DATE: 02/02/04

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 13, at (703) 305-6100.

Sincerely,

J. Wrice

Front End Processing Staff
Information Services Branch
Information Resources and Services Division

DP #: (298850) Decision #: 338773

DATA PACKAGE BEAN SHEET

Date: 18-Feb-2004

Cyfluvalinate 345 #71605

* * * Registration Information * * *

Registration: 11556-131 - CUTTER ULTRA INSECTICIDE CATTLE EAR TAG

Company: 11556 - BAYER HEALTHCARE LLC

Risk Manager: RM 13 - George Larocca - (703) 305-6100 Room# CM-2 206

Risk Manager Reviewer: Linda DeLuise LDELUISE

Sent Date: 04-Feb-2004 Calculated Due Date: 02-May-2004 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (345) FORMULA CHANGE;TECHNICAL;

Ingredients: 067501, Piperonyl butoxide(20%)

128831 118831, beta-cyfluthrin(8%)

Wrong pc. code

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 18-Feb-2004 Due Back:

DP Ingredient: 067501, Piperonyl butoxide

118831, beta-cyfluthrin

DP Title:

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

Assigned To	Date In	Date Out	
Organization: RD / TRB			Administrative Due Date: 03-Apr-2004
Team Name: Chem			Negotiated Due Date: 4-9-04
Reviewer Name:			Projected Completion Date:
Contractor Name:			

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Chem,

please review alternate source of pip

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUN 26 2003

Mr. F. Terry McNamara
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201

Subject: Amendment Updating Company Name and Adding Applicator Statement
CyLence® Ultra Cattle Insecticide Ear Tag
EPA Reg. No. 11556-131
Your Submission, Dated May 30, 2003

Dear Mr. McNamara:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy of the label is enclosed for your records.

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely,

Susan L. Stanton for

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Enclosure

Pouch

CYLENCE® ULTRA

INSECTICIDE CATTLE EAR TAG

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		Percent By Weight
Active Ingredients	Beta-cyfluthrin; Cyano (4-fluoro-3-phenyoxyphenyl) methyl 3-(2,2 – dichloroethenyl) 2, 2 – dimethylcyclopropane carboxylate	8%
	Piperonyl butoxide	20%
Other Ingredients	. . . . .	72%
Total	. . . . .	100%

Keep Out of Reach of Children

CAUTION

See Box For Precautionary Statements

Net Contents: 10 Tags - 0.5 oz per tag

Manufactured for
Bayer HealthCare, Animal Health Division
Shawnee Mission, KS 66201 U.S.A.

ACCEPTED

JUN 26 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 11556-131

EPA Est. No.
EPA Reg. No. 11556-131

Box (Front)

CYLENCE® ULTRA

INSECTICIDE CATTLE EAR TAG

For Use with Allflex Global Applicator with red pin and white clip.

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks

- Effective Against Face Flies and Pyrethroid Susceptible Horn Flies for up to 5 months.
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See Side Panel for Additional Precautionary Statements

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Bayer HealthCare, Animal Health Division
Shawnee Mission, KS 66201 U.S.A.

Box (Side Panel)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

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FIRST AID

If in Eyes:
- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present after the first 5 minutes, and then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If Swallowed:
- Call a poison control center or doctor immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin or clothing:
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If Inhaled:
- Move person to fresh air.
- If person is not breathing call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the product information center at 1-800-255-6826, or for emergency medical treatment information call 1-877-258-2280.

Environmental Hazards: This pesticide is toxic to fish. Do not contaminate water when disposing of used tags. Apply this product only as specified on the label.

Box (Back)

Directions for Use:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in the possession of the user at the time of pesticide application.

For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and dairy cattle (including lactating).

All mature animals in the herd should be tagged. For adequate control of horn flies attach one tag per animal. For optimum control of face flies, horn flies, gulf coast ticks, and spinose ear ticks, attach one tag to each ear (two per animal). Replace as necessary. CyLence® Ultra Insecticide Ear Tags have been proven to be effective against face and horn flies for up to five months.

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Apply as indicated (Figures 1-4). Calves less than 3 months of age should not be tagged as ear damage may result. Remove tags at end of fly season or prior to slaughter.

(Illustration)	(Illustration)	(Illustration)	(Illustration)
Figure 1	**Figure 2**	**Figure 3**	**Figure 4**
Disinfect pliers prior to use. Place male button onto pin until it projects through the tip.	Slide tag under the clip of the pliers by depressing the lever.	Position tag in the center portion of the front side of the ear.	Apply the tag between the second and third rib cartilage.

Continual exposure of horn flies to a single class of insecticide (e.g. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance it is important to rotate the class of insecticide used and/or the method of horn fly control on a seasonal basis. CyLence® Ultra Cattle Ear Tag contains the pyrethroid insecticide beta cyfluthrin plus piperonyl butoxide, which is an insecticide synergist.

Box (Back)

Storage and Disposal:

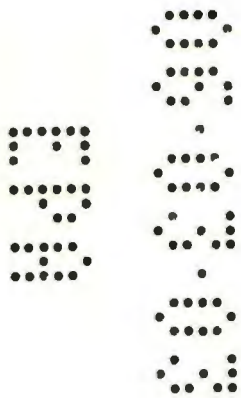
Do not contaminate water, food or feed by storage or disposal.

Storage: Store in cool place in original container. Opened pouches containing ear tags should be resealed for storage.

Pesticide Disposal: Waste (spent tags) resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Dispose of empty pouch in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned stay out of smoke.

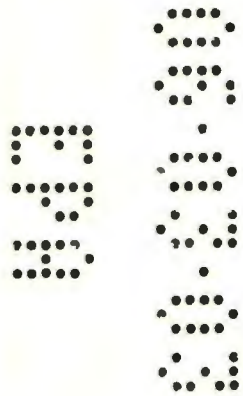
EPA Est. No.
EPA Reg. No. 11556-131



Box (Side Panel)

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division, warrants that this material conforms to the chemical description on the label. BAYER HEALTHCARE MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, and no agent of Bayer HealthCare, is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.



A

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number: 280970

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
11556-131	George LaRocca	☐ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
CyLence Ultra Insecticide Cattle Ear Tag	13	

5. Name and Address of Applicant *(Include ZIP Code)*

Bayer HealthCare LLC, Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See attached explanation.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Label accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
F. Terry McNamara	Director, Preclin Dev. & Regulatory Affairs	(913) 268-2588

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
for FTMcNamara	Director, Preclinical Development and Regulatory Affairs	
4. Typed Name	**5. Date**	
F. Terry McNamara	5-30-03	

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
280970

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant *(Include ZIP Code)* ☐ *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
4. Typed Name	5. Date	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: *Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.*

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. *EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.*
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
280970

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant *(Include ZIP Code)* ☐ *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
*Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

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5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. *The name and complete mailing address of such an agent must accompany this application.*
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SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

CYLENCE® ULTRA INSECTICIDE CATTLE EAR TAG
EPA Reg. No. 11556-131

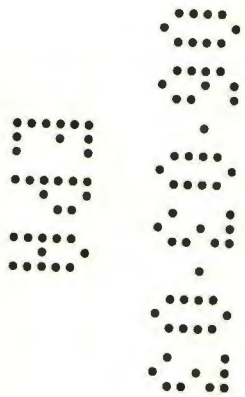
Explanation:

Enclosed are five (5) copies of the draft, proposed label for the above referenced product. The proposed label revises the previously stamped approved label dated January 28, 2003. Specifically, the proposed changes are:

1) Company name change from Bayer Corporation, Agriculture Division, Animal Health to Bayer HealthCare LLC, Animal Health Division. The name change was acknowledged by the Agency in their letter dated January 16, 2003.

2) The following statement has been added to the Directions for Use section and front panel for additional clarity:

   "Use the Allflex Global Applicator with the red pin and white clip to apply tags to cattle."



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 13, 2003

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

TERRY MCNAMARA
BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION
PO Box 390
SHAWNEE MISSION, KS 66201-0390

PRODUCT NAME: CUTTER ULTRA INSECTICIDE CATTLE EAR TAG
COMPANY NAME: BAYER HEALTHCARE LLC
OPP IDENTIFICATION NUMBER: 280970
EPA FILE SYMBOL: 11556-131
EPA RECEIPT DATE: 06/03/03

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 3, at (703) 305-7740.

Sincerely,

J Wrice

Front End Processing Staff
Information Services Branch
Information Resources and Services Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JAN 28 2003

Mr. F. Terry McNamara
Bayer Corporation
Agriculture Division, Animal Health
P.O. Box 390
Shawnee Mission, KS 66201

Subject: Amendment to Allow Use on Lactating Dairy Cattle
CyLence® Ultra Cattle Insecticide Ear Tag
EPA Reg. No. 11556-131
Your Resubmission, Dated October 21, 2002 and Additional Information Submitted by Email on January 28, 2003

Dear Mr. McNamara:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy of the label is enclosed for your records.

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely,

Susan L. Stanton for

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Enclosure

Pouch

CYLENCE® ULTRA

INSECTICIDE CATTLE EAR TAG

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks for Up to Five Months.

		Percent By Weight
Active Ingredients	Beta-cyfluthrin; Cyano (4-fluoro-3-phenyoxyphenyl) methyl 3-(2,2 – dichloroethenyl) 2, 2 – dimethylcyclopropane carboxylate	8%
	Piperonyl butoxide	20%
Other Ingredients	. . . . .	72%
Total	. . . . .	100%

ACCEPTED

JAN 28 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 11556-131

Keep Out of Reach of Children

CAUTION

See Box For Precautionary Statements

Net Contents: 10 Tags - 0.5 oz per tag
Manufactured for
Bayer Corporation, Agriculture Division, Animal Health
Shawnee Mission, KS 66201 U.S.A.

EPA Est. No.
EPA Reg. No. 11556-131

Box (Front)

CYLENCE® ULTRA

INSECTICIDE CATTLE EAR TAG

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks

- Effective Against Face Flies and Pyrethroid Susceptible Horn Flies for up to 5 months.
- Kills and Repels Face Flies – mechanical vector of *Moraxella bovis* bacteria causing "pink eye" of cattle
- Synergized for extra performance

		Percent By Weight
Active Ingredients	Beta-cyfluthrin; Cyano (4-fluoro-3-phenyoxyphenyl) methyl 3-(2,2 – dichloroethenyl) 2, 2 – dimethylcyclopropane carboxylate	8%
	Piperonyl Butoxide Technical	20%
Other Ingredients	. . . . .	72%
Total	. . . . .	100%

Keep Out of Reach of Children

CAUTION

See Side Panel for Additional Precautionary Statements

Bayer Corporation, Agriculture Division, Animal Health
Shawnee Mission, KS 66201 U.S.A.

Net Contents: 2 pouches of 10 tags each – 0.5 oz per tag

Box (Side Panel)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

May cause eye irritation. Harmful if swallowed, inhaled or absorbed through the skin. Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wear nonpermeable protective gloves when applying or removing tags. Wash thoroughly with soap and water after use and before eating, drinking or using tobacco.

FIRST AID

If in Eyes:
- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present after the first 5 minutes, and then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If Swallowed:
- Call a poison control center or doctor immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin or clothing:
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If Inhaled:
- Move person to fresh air.
- If person is not breathing call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the product information center at 1-800-255-6826, or for emergency medical treatment information call 1-877-258-2280.

Environmental Hazards: This pesticide is toxic to fish. Do not contaminate water when disposing of used tags. Apply this product only as specified on the label.

Box (Back)

Directions for Use:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in the possession of the user at the time of pesticide application.

For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and dairy cattle (including lactating).

All mature animals in the herd should be tagged. For adequate control of horn flies attach one tag per animal. For optimum control of face flies, horn flies, gulf coast ticks, and spinose ear ticks, attach one tag to each ear (two per animal). Replace as necessary. CyLence® Ultra Insecticide Ear Tags have been proven to be effective against face and horn flies for up to five months.

Apply as indicated (Figures 1-4). Calves less than 3 months of age should not be tagged as ear damage may result. Remove tags at end of fly season or prior to slaughter.

Figure 1

Disinfect pliers prior to use. Place male button onto pin until it projects through the tip.

Figure 2

Slide tag under the clip of the pliers by depressing the lever.

Figure 3

Position tag in the center portion of the front side of the ear.

Figure 4

Apply the tag between the second and third rib cartilage.

Continual exposure of horn flies to a single class of insecticide (e.g. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance it is important to rotate the class of insecticide used and/or the method of horn fly control on a seasonal basis. CyLence® Ultra Cattle Ear Tag contains the pyrethroid insecticide beta cyfluthrin plus piperonyl butoxide, which is an insecticide synergist.

Storage and Disposal:

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in cool place in original container. Opened pouches containing ear tags should be resealed for storage.

Pesticide Disposal: Waste (spent tags) resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Dispose of empty pouch in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned stay out of smoke.

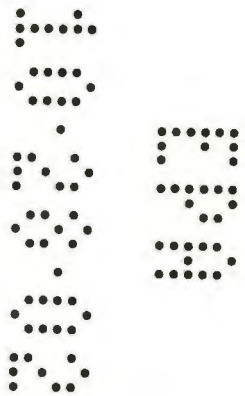
EPA Est. No.
EPA Reg. No. 11556-131

Box (Side Panel)

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, and no agent of Bayer Corporation, is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Bayer Corporation, Agriculture Division, Animal Health
Shawnee Mission, KS 66201 U.S.A.



Greg Gagliano
<greg.gagliano.b@bayer.com>

To: Susan Stanton/DC/USEPA/US@EPA
cc:
Subject: Calculations

01/28/2003 10:26 AM

Dear Susan,

As we discussed this morning, here are some calculations showing that the total amount of piperonyl butoxide (PBO) released from two CyLence Ultra ear tags (EPA Reg. No. 11556-131) during a 5-month treatment period compared to a typical PBO-containing pour-on product. The pour-on used in this example is UltraBoss Pour-On Insecticide (EPA Reg. No. 773-84) which contains 5% PBO and has a label claim for use on lactating dairy cattle. It has a maximum application rate of 30 mL per animal every 14 days.

For CyLence Ultra the total amount of PBO applied per animal would be:

20% PBO
2 ear tags applied for a 5 month period
1 ear tag weighs 0.5 oz

0.2 PBO x 0.5 oz/tag x 28.3 g/oz x 2 tags/cow = 5.7 g PBO per cow per 5-month period

For UltraBoss Pour-on the total amount of PBO applied per animal would be:

5% PBO
30 mL applied per animal per treatment
2 treatments per month (every 14 days maximum)
Assume product density is 1 g/mL since most liquid pesticides have densities ranging from 0.9 to 1.1.

Confirmed. L.L.

0.05 ~~0.5~~ PBO x 30 mL/cow x 1 g/mL x 2 treatments/mo. x 5 months = 15.0 ~~150~~ g PBO per cow per 5-month period

Clearly, cattle treated for a 5-month period using a typical PBO-containing pour-on product to control flies receive a higher dose of PBO compared to the a cattle treated with two (2) CyLence Ultra Ear Tags for the same 5-month period.
I hope this rationale supports our request to add lactating dairy cattle to the label for CyLence Ultra Ear Tags. Please contact me if you need additional information or have any questions.

Thank you very much for your assistance in handling this request!

Sincerely,

Greg Gagliano
Manager, Environmental Research and EPA Regulatory Affairs
Bayer HealthCare, LLC
Animal Health Division

Phone: 913-268-2751
Fax: 913-268-2135
e-mail: greg.gagliano.b@bayer.com

A B

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number: 301692

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
11556-131	George LaRocca	☐ None ☐ Restricted
4. Company/Product (Name) CyLence Ultra Insecticide Cattle Ear Tag	**PM#** 13	

5. Name and Address of Applicant *(Include ZIP Code)*
Bayer Corporation, Animal Health, Agriculture Division
P.O. Box 390
Shawnee Mission, KS 66201

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See attached explanation.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information ☐ Label ☐ Container
4. Size(s) Retail Container
5. Location of Label Directions ☐ On Label ☐ On Label accompanying product
6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
F. Terry McNamara	Director, Preclin Dev. and EPA Reg. Affairs	(913) 268-2588

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received
F. Terry McNamara	Director, Preclinical Development and EPA Reg. Affairs	(Stamped)
4. Typed Name F. Terry McNamara	**5. Date** October 21, 2002	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
301692

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	

5. Name and Address of Applicant *(Include ZIP Code)*

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
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☐ Final printed labels in response to Agency letter dated _____
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☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
*Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
4. Typed Name	5. Date

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
391692

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
4. Company/Product (Name)	PM# 0	☐ None ☐ Restricted

5. Name and Address of Applicant *(Include ZIP Code)*

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
● Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
● *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
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3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
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1-5. Self-explanatory.
6. EPA Use Only.

A

B

Attachment for Application for Pesticide Registration
CyLence® Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-131

Enclosed with this application are five (5) copies of proposed draft labeling for Bayer's CyLence® Ultra Insecticide Cattle Ear Tag product (EPA Reg. No. 11556-131). The draft label is identical to the current stamped accepted label, except for a change to the use statements on the foil pouch, the front label and under "Directions for Use". The change is from use on non-lactating dairy cattle to lactating dairy cattle.

Specifically, the following statements were changed:

On the foil pouch and on the front panel:

> Change from "For use on Beef and Non-Lactating Dairy Cattle…" to "For use on Beef and Dairy Cattle (including lactating)…"

Under the "Directions for Use" section:

> Change from "For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and non-lactating dairy cattle" to "For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and dairy cattle (including lactating)."

In explanation, the addition of lactating dairy cattle will not result in any additional exposure because of the following reasons. First, both active ingredients in the CyLence Ultra ear tag are currently registered for use on lactating dairy cattle. Lactating dairy cattle are already on the cyfluthrin ear tag – Cutter Gold (EPA Reg. No. 11556-106 (note that beta cyfluthrin is two of the isomeric pairs present in cyfluthrin). Moreover, cyfluthrin is the active ingredient in CyLence Pour-On, EPA Reg. No. 11556-107. This liquid formulation of cyfluthrin is registered for direct pour-on application to lactating dairy cattle (CyLence is registered for use on all cattle).

Piperonyl butoxide is registered for use on lactating dairy cattle in Python Magnum Cattle Ear Tags (EPA Reg. No. 39039-11). The Python Magnum product weight is 0.5 oz (15.4 grams) per tag and contains 20% piperonyl butoxide (copy of label attached). Likewise, Bayer's CyLence Ultra product weight is 0.5 oz per tag and contains 20% piperonyl butoxide. This information should satisfy the Agency's concern in their letter dated June 27, 2002 (copy of letter attached).

In general, ear tags are a very specific, rather limited use tool for the cattle industry. The number of cattle in the US is not increasing, nor is the total number of ear tags being used. The total ear tag market is a limited, stagnant market; when a new ear tag is introduced it is used instead of other ear tags already on the market, i.e. – new ear tags simply displace the use of existing ear tags on the market. In the instance of the CyLence Ultra ear tag, it will simply displace the use other tags on the market.

Tolerances for cyfluthrin (beta cyfluthrin) and piperonyl butoxide in milk are already established at 15 ppm and 0.25 ppm, respectively.

The use statement changes listed above use the exact same wording as on the currently approved cyfluthrin ear tag label (EPA Reg. No. 11556-106).

via Federal Express – Express Saver - 10/24/02

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attachments: Application for Pesticide Amendment CyLence Ultra Cattle Insecticide Ear Tag (Reg. No. 11556-131)
Draft Labeling (Five Copies)
Copy of Python Magnum Cattle Ear Tag Label (Reg. No. 39039-11)
Copy of EPA Letter dated June 27, 2002

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

10/31/2002

F.T. MCNAMARA
BAYER CORP
P.O. BOX 390
SHAWNEE MISSION KS 662010390

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: CYLENCE ULTRA INSECTICIDE CATTLE EAR TAG
COMPANY NAME: BAYER CORP
OPP IDENTIFICATION NUMBER: 301692
EPA REGISTRATION NUMBER: 11556-131
EPA RECEIPT DATE: 10/28/2002

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Insecticide Branch, Product Manager 03, at (703) 305-6891.

Sincerely,

Front End Processing Staff
Information Services Branch
Program Management and Support Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUN 27 2002

Mr. F. Terry McNamara
Bayer Corporation
Agriculture Division, Animal Health
P.O. Box 390
Shawnee Mission, KS 66201

Subject: I. Acute Dermal Toxicity Study (MRID#456407-01)
Your Submission Dated March 26, 2002

II. Amendment to Allow Use on Lactating Dairy Cattle
Your Submission Dated March 19, 2002

CyLence® Ultra Cattle Insecticide Ear Tag
EPA Reg. No. 11556-131

Dear Mr. McNamara:

I. Acute Dermal Toxicity Study (MRID#456407-01):

The above study has been reviewed and determined to be acceptable. A copy of the review, dated June 7, 2002, is enclosed for your records. This study satisfies condition "1)" of the Notice of Registration, dated November 2, 2001. Based on the study results, the product has been classified in Category III for acute dermal toxicity. The previously accepted labeling includes appropriate dermal precautionary and First Aid statements for Category III products. Therefore, no changes are required based on the new study.

II. Amendment to Allow Use on Lactating Dairy Cattle:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable for the following reasons:

1. The cyfluthrin products which you cited (in particular, EPA Reg. No. 11556-106) support the application of a 14 g (0.5 oz.) 8% beta-Cyfluthrin ear tag product on lactating dairy cattle. However, the piperonyl butoxide (PBO) products you cited do not support the application of a 14 g 20% PBO product on lactating dairy cattle. EPA Reg. No. 67517-36 is a 10 g ear tag product containing only 2% PBO (10% as concentrated as the subject product with less product per tag). EPA Reg. No. 39039-4 is a 20% PBO product.; however, each tag contains only 9.5 g (only 2/3 the dose using your product). The other product you cited (EPA Reg. No. 47000-54) contains 0.1% PBO and is applied as a spray at up to 2 oz. per animal (0.002 oz. of PBO per animal). Each of your ear tags contains 0.1 oz. of PBO (20% of 0.5 oz.), considerably more than the amount applied per animal using the cited spray product.

You must either cite a registered product where EPA has approved the application of PBO on lactating dairy cattle at rates/concentrations equivalent to those of the subject product or submit/cite data showing that the use of your product on lactating dairy cattle will not result in milk residues in excess of the existing PBO milk tolerance.

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Enclosure

Pouch

CYLENCE® ULTRA

INSECTICIDE CATTLE EAR TAG

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks for Up to Five Months.

		Percent By Weight
Active Ingredients	Beta-cyfluthrin; Cyano (4-fluoro-3-phenyoxyphenyl) methyl 3-(2,2 – dichloroethenyl) 2, 2 – dimethylcyclopropane carboxylate	8%
	Piperonyl butoxide	20%
Other Ingredients	. . . . .	72%
Total	. . . . .	100%

Keep Out of Reach of Children

CAUTION

See Box For Precautionary Statements

Net Contents: 10 Tags - 0.5 oz per tag
Manufactured for
Bayer Corporation, Agriculture Division, Animal Health
Shawnee Mission, KS 66201 U.S.A.

EPA Est. No.
EPA Reg. No. 11556-131

Unacceptable –

PBO rate on lactating dairy cattle not supported by cited products. Hold labels until company responds.

Box (Front)

CYLENCE® ULTRA

INSECTICIDE CATTLE EAR TAG

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks

- Effective Against Face Flies and Pyrethroid Susceptible Horn Flies for up to 5 months.
- Kills and Repels Face Flies – mechanical vector of *Moraxella bovis* bacteria causing "pink eye" of cattle
- Synergized for extra performance

		Percent By Weight
Active Ingredients	Beta-cyfluthrin; Cyano (4-fluoro-3-phenyoxyphenyl) methyl 3-(2,2 – dichloroethenyl) 2, 2 – dimethylcyclopropane carboxylate	8%
	Piperonyl Butoxide Technical	20%
Other Ingredients	. . . . .	72%
Total	. . . . .	100%

Keep Out of Reach of Children

CAUTION

See Side Panel for Additional Precautionary Statements

Bayer Corporation, Agriculture Division, Animal Health
Shawnee Mission, KS 66201 U.S.A.

Net Contents: 2 pouches of 10 tags each – 0.5 oz per tag

Box (Side Panel)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

May cause eye irritation. Harmful if swallowed, inhaled or absorbed through the skin. Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wear nonpermeable protective gloves when applying or removing tags. Wash thoroughly with soap and water after use and before eating, drinking or using tobacco.

FIRST AID

If in Eyes:
- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present after the first 5 minutes, and then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If Swallowed:
- Call a poison control center or doctor immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin or clothing:
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If Inhaled:
- Move person to fresh air.
- If person is not breathing call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the product information center at 1-800-255-6826, or for emergency medical treatment information call 1-877-258-2280.

Environmental Hazards: This pesticide is toxic to fish. Do not contaminate water when disposing of used tags. Apply this product only as specified on the label.

Box (Back)

Directions for Use:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in the possession of the user at the time of pesticide application.

For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and dairy cattle (including lactating).

All mature animals in the herd should be tagged. For adequate control of horn flies attach one tag per animal. For optimum control of face flies, horn flies, gulf coast ticks, and spinose ear ticks, attach one tag to each ear (two per animal). Replace as necessary. CyLence® Ultra Insecticide Ear Tags have been proven to be effective against face and horn flies for up to five months.

Apply as indicated (Figures 1-4). Calves less than 3 months of age should not be tagged as ear damage may result. Remove tags at end of fly season or prior to slaughter.

Figure 1

Disinfect pliers prior to use. Place male button onto pin until it projects through the tip.

Figure 2

Slide tag under the clip of the pliers by depressing the lever.

Figure 3

Position tag in the center portion of the front side of the ear.

Figure 4

Apply the tag between the second and third rib cartilage.

Continual exposure of horn flies to a single class of insecticide (e.g. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance it is important to rotate the class of insecticide used and/or the method of horn fly control on a seasonal basis. CyLence® Ultra Cattle Ear Tag contains the pyrethroid insecticide beta cyfluthrin plus piperonyl butoxide, which is an insecticide synergist.

Storage and Disposal:

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in cool place in original container. Opened pouches containing ear tags should be resealed for storage.

Pesticide Disposal: Waste (spent tags) resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Dispose of empty pouch in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned stay out of smoke.

EPA Est. No.
EPA Reg. No. 11556-131

Box (Side Panel)

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, and no agent of Bayer Corporation, is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Bayer Corporation, Agriculture Division, Animal Health
Shawnee Mission, KS 66201 U.S.A.

5613619

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number: 293963

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
11556-131	George LaRocca	[ ] None [ ] Restricted
4. Company/Product (Name) CyLence Ultra Insecticide Cattle Ear Tag	PM# 03	

5. Name and Address of Applicant *(Include ZIP Code)*
Bayer Corporation, Animal Health, Agriculture Division
P.O. Box 390
Shawnee Mission, KS 66201

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

- [x] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See attached explanation.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Label accompanying product

6. Menner in Which Label is Affixed to Product [ ] Lithograph [ ] Peper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
F. Terry McNamara	Director, Preclin Dev. and EPA Reg. Affairs	(913) 268-2588

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
F. Terry McNamara	Director, Preclinical Development and EPA Reg. Affairs	
4. Typed Name F. Terry McNamara	**5. Date** March 19, 2002	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
293963

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	

5. Name and Address of Applicant *(Include ZIP Code)*

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
*Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

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PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

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INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

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Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
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SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.

6. **EPA Use Only.**

56136-19

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number: 293963

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
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3. Proposed Classification - Specify the proposed classification of this product.
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SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

Attachment for Application for Pesticide Registration
CyLence® Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-131

Enclosed with this application are five (5) copies of proposed draft labeling for Bayer's CyLence® Ultra Insecticide Cattle Ear Tag product (EPA Reg. No. 11556-131). The draft label is identical to the current stamped accepted label, except for a change to the use statements on the foil pouch, the front label and under "Directions for Use". The change is from use on non-lactating dairy cattle to lactating dairy cattle.

Specifically, the following statements were changed:

On the foil pouch and on the front panel:

Change from "For use on Beef and Non-Lactating Dairy Cattle…" to "For use on Beef and Dairy Cattle (including lactating)…"

Under the "Directions for Use" section:

Change from "For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and non-lactating dairy cattle" to "For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and dairy cattle (including lactating)."

In explanation, the addition of lactating dairy cattle will not result in any additional exposure because of the following reasons. First, both active ingredients in the CyLence Ultra ear tag are currently registered for use on lactating dairy cattle. Lactating dairy cattle are already on the cyfluthrin ear tag – Cutter Gold (EPA Reg. No. 11556-106 (note that beta cyfluthrin is two of the isomeric pairs present in cyfluthrin). Moreover, cyfluthrin is the active ingredient in CyLence Pour-On, EPA Reg. No. 11556-107. This liquid formulation of cyfluthrin is registered for direct pour-on application to lactating dairy cattle (CyLence is registered for use on all cattle). Piperonyl butoxide is registered for use on lactating dairy cattle in Python Cattle Ear Tags (EPA Reg. No. 39039-4), Dual Gard Insecticide Cattle Ear Tags (EPA Reg. No. 67517-36), and Dairy Cattle Spray (EPA Reg. No. 47000-54).

In general, ear tags are a very specific, rather limited use tool for the cattle industry. The number of cattle in the US is not increasing, nor is the total number of ear tags being used. The total ear tag market is a limited, stagnant market; when a new ear tag is introduced it is used instead of other ear tags already on the market, i.e. – new ear tags simply displace the use of existing ear tags on the market. In the instance of the CyLence Ultra ear tag, it will simply displace the use other tags on the market.

Tolerances for cyfluthrin (beta cyfluthrin) and piperonyl butoxide in milk are already established at 15 ppm and 0.25 ppm, respectively.

The use statement changes listed above use the exact same wording as on the currently approved cyfluthrin ear tag label (EPA Reg. No. 11556-106).

A B

via 2nd Day Federal Express 03/19/02

Document Processing Desk (AMEND)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Enclosure: Application for Pesticide Amendment –
CyLence® Ultra Insecticide Cattle Ear Tag
(EPA Reg. No. 11556-131) – with five copies draft labeling

#13467

DP BARCODE: D282351

CASE: 069043 DATA PACKAGE RECORD DATE: 04/12/02
SUBMISSION: S614017 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 305 TECH-LBL REV AMND DATA RE
RANKING : 10 POINTS ()
CHEMICALS: 067501 Piperonyl butoxide 20.0000%
128831 Cyfluthrin 8.0000%

ID#: 011556-00131 Cutter Ultra Cattle Insecticide Ear Tag
COMPANY: 011556 BAYER CORP
PRODUCT MANAGER: 03 ARNOLD LAYNE 703-305-6249 ROOM: CM2 212
PM TEAM REVIEWER: SUSAN STANTON 703-305-5218 ROOM: CM2 237
RECEIVED DATE: 03/29/02 DUE OUT DATE: 09/25/02

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 282351 EXPEDITE: N DATE SENT: 04/12/02 DATE RET.: / /
CHEMICAL: 067501 Piperonyl butoxide
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : RD	/ /	/ /
BRAN: TRB	/ /	/ /
SECT: TOX	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 07/11/02
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

The originally submitted dermal toxicity study for this product (MRID#454446-01) was reviewed by TRB and found to be unacceptable (A copy of the review is attached). As a condition of registration, the company was required to submit a new dermal study. The new study (MRID#456407-01) is attached for your review. Copies of the CSF and label for this product are included for your information. If you need anything else, please let me know.

Thanks,
Susan Stanton

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

PRINT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

07/JUNE/2002

MEMORANDUM

Subject:	Name of Pesticide Product:	Cutter Ultra Insecticide Cattle Ear Tag
	EPA Reg. No. /File Symbol:	11556-131
	DP Barcode:	D282351
	Case No:	069043
	PC Code:	067501, 128831
From:	Eugenia McAndrew, Biologist Technical Review Branch Registration Division (7505C)	
To:	Susan Stanton, PM Team 03 Insecticide Branch Registration Division (7505C)	
Applicant:	Bayer Corporation Agriculture Division P.O. Box 390 Shawnee Mission, KS 66201-0390	

FORMULATION FROM LABEL:

	Active Ingredient(s):	% by wt.
128831	Cyano (4-fluoro-3-phenoxyphenyl) methyl 3-(2,2-dichloroethenyl) 2,2-dimethylcyclopropane	8
067501	Piperonyl butoxide	20
	Inert Ingredient(s):	72
	Total:	100%

ACTION REQUESTED: "The originally submitted dermal toxicity study for this product (MRID 45444601) was reviewed by TRB and found unacceptable. As a condition of registration, the company was required to submit a new dermal study. The new study (MRID 45640701) is attached for your review."

BACKGROUND: Bayer Corporation has submitted an acute dermal toxicity study (MRID 45640701) to support registration of Cutter Ultra Insecticide Cattle Ear Tag, EPA Reg. No.11556-131. A previous dermal toxicity study was classified as unacceptable in a TRB memorandum (McAndrew; D277606; EPA Reg. No. 11556-RGR; 13/SEPT/2001). This new study was conducted at Bayer Corporation Agriculture Division, Toxicology, Stilwell, Kansas. The product was given a conditional registration. The other five acute toxicity studies were waived. Please refer to the 13/SEPT/2001 memorandum for the complete explanation.

RECOMMENDATIONS: The acute dermal toxicity study has been reviewed and is classified as acceptable. The toxicity category for dermal toxicity is category III.

The acute toxicity profile for Cutter Ultra Insecticide Cattle Ear Tag, EPA Reg. No.11556-131, is as follows:

acute oral toxicity	IV	Waived	
acute dermal toxicity	III	Acceptable	MRID 45640701
acute inhalation toxicity	IV	Waived	
primary eye irritation	IV	Waived	
primary skin irritation	IV	Waived	
dermal sensitization	--	Waived	

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System.

PRODUCT ID #: 011556-00131

PRODUCT NAME: CUTTER ULTRA CATTLE INSECTICIDE EAR TAG

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: CAUTION

Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

First Aid:

If on skin:
-Take off contaminated clothing.
-Rinse skin immediately with plenty of water for 15-20 minutes.
-Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

DATA EVALUATION RECORD

STUDY TYPE: ACUTE DERMAL TOXICITY TESTING (870.1200 formerly §81-2)

Product Manager: 03 **Reviewer:** Eugenia McAndrew

TEST MATERIAL PURITY: M779 Cattle Ear Tag (20% PBO and 8% beta cyfluthrin)

CITATION: Johnson, K.L. (2002); M779 Cattle Ear Tag; acute dermal LD_{50} in the rat. Bayer Corporation Agriculture Division Toxicology, Stilwell, Kansas. Laboratory Report Number 02-A22-JC. March 19, 2002. MRID 45640701. Unpublished.

SPONSOR: Bayer Corporation, Agriculture Division, P.O. Box 390, Shawnee Mission, KS 66201-0390

EXECUTIVE SUMMARY: In an acute dermal toxicity study, two control groups and one test group of Wistar Hanover (Crl: WI[Glx/BRL/HAN]GS BR) rats (Age: 11 weeks; Weight: males: 244-280 g; females: 190-215 g; Source: Charles River Laboratories, Inc., Raleigh, NC) were dermally exposed to a single application of M779 Cattle Ear Tag (20% PBO and 8% beta cyfluthrin; Lot No. M-98-02-M779-99-02-59: light purple tag) for 24 hours. Three groups of six animals/sex were exposed to either 0 mg/kg (collared), 0 mg/kg (uncollared) or 2000 mg/kg (limit dose). The test substance (cattle ear tag) was moistened with 50 μL of deionized water and applied directly to approximately 10% of the body surface area of each test group animal. Body weights were determined prior to dosing and on days 7 and 14. Animals were observed for clinical signs of toxicity and mortality twice daily for five days and then once daily for the remainder of 14 days. Gross necropsies were performed on all animals.

Dermal LD_{50} Males = > 2000 mg/kg (observed); Dermal LD_{50} Females = > 2000 mg/kg (observed)

M779 Cattle Ear Tag is classified as Toxicity Category III based on the observed LD_{50} values in both sexes.

All animals survived the study. All animals showed body weight gains. Lacrimal and nasal staining and perigenital staining were noted in one control group and in the 2000 mg/kg group. Thinning hair was noted in one treated female and one control female. Alopecia was noted in one treated female. Two treated females exhibited a progression of redness, sore and scabbing at the dose sites. No evidence of systemic toxicity was observed. At necropsy, no gross abnormalities were noted in the treated group. A crusty red zone in the ventral abdominal area was noted in one control group male.

This study is classified as Acceptable (870.1200) and satisfies the guideline requirement for an acute dermal study in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
0 (collared)	0/6	0/6	0/6
0 (uncollared)	0/6	0/6	0/6
2000 (collared)	0/6	0/6	0/6

OBSERVATIONS: All animals survived the study. All animals showed body weight gains. Lacrimal and nasal staining and perigenital staining were noted in one control group and in the 2000 mg/kg group. Thinning hair was noted in one treated female and one control female. Alopecia was noted in one treated female. Two treated females exhibited a progression of redness, sore and scabbing at the dose sites. No evidence of systemic toxicity was observed.

GROSS NECROPSY: At necropsy, no gross abnormalities were noted in the treated group. A crusty red zone in the ventral abdominal area was noted in one control group male.

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D282351
2. **PC CODE:** 067501, 128831
3. **CURRENT DATE:** 07/JUNE/2002
4. **TEST MATERIAL:** M779 Cattle Ear Tag (20% PBO and 8% beta cyfluthrin; Lot No. M-98-02-M779-99-02-59; light purple tag)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute dermal toxicity/rabbit Bayer Corp. Agriculture Division Toxicology 02-A22-JC/3-19-02	45640701	LD_{50} > 2000 mg/kg (males females combined)	III	A

Core Grade Key: **A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated**

MAY 28 2002

Mr. F.T. McNamara
Bayer Corporation
8400 Hawthorn Road
P.O. Box 4913
Kansas City, Missouri 64120-0013

Dear Mr. McNamara:

Subject: Amendment - Confidential Statement of Formula- Basic Cutter Ultra Cattle Insecticide Ear Tag
EPA Registration No. 11556-131
Your submission dated March 8, 2002

Your basic Confidential Statement of Formula

(CSF)dated March 8, 2002 has been reviewed is acceptable.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505)

DATE OUT: 8/MAY/2002

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]
DP BARCODE No.: D281957 REG./File Symbol No.: 11556-131
PRODUCT NAME: Cutter Ultra Cattle Insecticide Ear Tag
ACTION CODE: 345, Tech-Form. Change, Amend

FROM: Linda L. Kutney, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505C)

TO: Arnold Layne, Linda DeLuise PM-3
Insecticide Branch/RD(7505C)

INTRODUCTION:

The Registrant, Bayer Corp, is submitting a revised basic CSF, dated 3/8/02, for their insecticide product, Cutter Ultra Cattle Insecticide Ear Tag , Reg No 11556-131. containing the following label claim:

8% Cyano (4-fluoro-3-phenyoxyphenyl) methyl 3- (2,2-dichloroethenyl) 2,2-dimethylcloproane carboxylate

20% Piperonyl Butoxide (PBO)

Use of Cutter Ultra Cattle Insecticide Ear Tag is considered a non-food use.

SUMMARY OF FINDINGS:

The proposed 3/8/02 basic CSF contains three proposed changes from the previously accepted 6/28/01 basic CSF:

1) Name change from "Cutter Ultra" to "CyLence Ultra."

2) Change of supplier of an approved inert.

3) Change of PBO Reg. No. from [redacted]

CONCLUSIONS:

The proposed 3/28/02 CSF is acceptable, from a product chemistry point of view. The three proposed changes do not effect the physical chemical content of the final Cutter Ultra Cattle Insecticide Ear Tag product.

Inert ingredient information may be entitled to confidential treatment

CONFIDENTIAL APPENDIX:

The inert which must be added to the Agency database is

[redacted]

The MSDS indicates that it is comprised of [redacted]

Product ingredient source information may be entitled to confidential treatment

NOTE TO THE PM:

[redacted]

345-LD-Chem

George LaRocca
3/18/02

FRONT END PROCESSING APPLICATION INFORMATION CHECK LIST

PM 03

EPA COMPANT NUMBER 11556-131

EPA REGISTRATION NUMBER STATUS (FOR AMENDMENTS) ACTIVE ✓ CANCELLED_____

NOT IN REFS_____

"ME-TOO" CITED PRODUCT STATUS ACTIVE_____ CANCELLED_____

NOT IN REFS_____

OPP# 282828 DATE 3-14-02

A

B

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- ☐ Registration
- ☑ Amendment
- ☐ Other

OPP Identifier Number: 282828

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
11556-131	George LaRocca	☐ None ☐ Restricted
4. Company/Product (Name) CyLence Ultra Cattle Insecticide Ear Tag	**PM#** 03	

5. Name and Address of Applicant *(Include ZIP Code)*
Bayer Corporation, Animal Health, Agriculture Division
P.O. Box 390
Shawnee Mission, KS 66201

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

- ☑ Amendment - Explain below.
- ☐ Resubmission in response to Agency letter dated _____
- ☐ Notification - Explain below.
- ☐ Final printed labels in repsonse to Agency letter dated _____
- ☐ "Me Too" Application.
- ☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See attached explanation.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Label accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
F. Terry McNamara	Director, Preclin Dev. and EPA Reg. Affairs	(913) 268-2588

Certification

I certify that the statements I heve made on this form end all attachments thereto ere true, accurate and complete. I acknowledge that any knowlingllly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
F. Terry McNamara	Director, Preclinical Development and EPA Reg. Affairs	
4. Typed Name F. Terry McNamara	**5. Date** March 8, 2002	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
282828

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
4. Company/Product (Name)	PM#	☐ None ☐ Restricted

5. Name and Address of Applicant *(Include ZIP Code)*

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
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☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
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*Certification must submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

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I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

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PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of dreft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

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1. Company/Product Number - Insert your Company Number, if one hes been assigned by EPA. This number may have been assigned to you es a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

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SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
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1-5. Self-explanatory.
6. EPA Use Only.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
282828

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
4. Company/Product (Name)	PM#	☐ None ☐ Restricted

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1-5. Self-explanatory.
6. EPA Use Only.

A

B

Bayer

Agriculture Division

Animal Health

Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390
Phone 913 268-2000

via Federal Express – Express Saver

March 8, 2002

Mr. George LaRocca
Product Manager
Registration Division (H7505C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Amendment for Confidential Statement of Formula
CyLence® Ultra Cattle Insecticide Ear Tag, EPA Reg. No. 11556-131

Dear Mr. LaRocca:

Attached please find a Application for Amendment for the above referenced product. Since the proposed change in active ingredient is a 100% repack (absolutely identical to the currently listed a.i.), there will be no change in the formulation or efficacy of the product.

If you have any questions, please do not hesitate to call me at (913) 268-2588 or Greg Gagliano at (913) 268-2751.

Sincerely,

F. Terry McNamara

F. Terry McNamara
Director, Preclinical Development & EPA Regulatory Affairs

FTM:GGG/lt

Attachment for Application for Pesticide Registration

CyLence® Ultra Cattle Insecticide Ear Tag, EPA Reg. No. 11556-131

Enclosed with this application are two (2) copies of the proposed Confidential Statement of Formula (CSF) for Bayer's CyLence® Ultra Cattle Insecticide Ear Tag product (EPA Reg. No. 11556-131).

The proposed changes are:

1) Change the active ingredient Piperonyl Butoxide (PBO) from [redacted]

2) Change the supplier name for [redacted]

3) Changed the product name from "Cutter Ultra" to "CyLence Ultra". This name change was made by Notification to the Agency, dated January 7, 2002.

Pages 82-87 – *Product ingredient source information may be entitled to confidential treatment*

13402

DP BARCODE: D281957

CASE: 069043 DATA PACKAGE RECORD DATE: 05/09/02
SUBMISSION: S612928 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 345 TECH-FORMULA CHANGE AMND
RANKING : 5 POINTS ()
CHEMICALS: 067501 Piperonyl butoxide 20.0000%
128831 Cyfluthrin 8.0000%

ID#: 011556-00131 Cutter Ultra Cattle Insecticide Ear Tag
COMPANY: 011556 BAYER CORP
PRODUCT MANAGER: 03 ARNOLD LAYNE 703-305-6249 ROOM: CM2 212
PM TEAM REVIEWER: LINDA DELUISE 703-305-5428 ROOM: CM2 200
RECEIVED DATE: 03/11/02 DUE OUT DATE: 06/09/02

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 281957 EXPEDITE: N DATE SENT: 03/27/02 DATE RET.: 05/08/02
CHEMICAL: 067501 Piperonyl butoxide
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 05/11/02
DIV : RD	03/27/02	05/08/02	NEGOT DATE: 05/23/02
BRAN: TRB	04/08/02	05/08/02	PROJ DATE: / /
SECT: CHEM	04/08/02	05/08/02	
REVR : LKUTNEY	05/03/02	05/08/02	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

is new csf ok

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

5614017

APR 8 2002

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

BAYER CORP.
AGRIC.DIV.-ANIMAL HEALTH
P.O. BOX 390
SHAWNEE MISSION, KS 662010390

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 03/29/02. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Bayer

Agriculture Division

Animal Health

Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390
Phone: 913 268-2000

456407-00

via Federal Express

March 26, 2002

Mr. George LaRocca
Product Manager
Registration Division (H7505C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Acute Dermal Toxicity Study for
CyLence® Ultra Cattle Insecticide Ear Tag, EPA Reg. No. 11556-131

Dear Mr. LaRocca:

Enclosed please find three (3) copies of the acute dermal toxicity study report for the above referenced product. This study was conducted in agreement with the Agency to satisfy the condition-of-registration dated November 2, 2001.

If you have any questions, please do not hesitate to call me at (913) 268-2588 or Greg Gagliano at (913) 268-2751.

Sincerely,

for

F. Terry McNamara
Director, Preclinical Development & EPA Regulatory Affairs

FTM:GGG/lt

Transmittal Document

1. Name and Address of Submitter
Bayer Corporation
Animal Health
Box 390
Shawnee Mission, Kansas 66201-0390

for

F. Terry McNamara
Director, Preclinical Development and EPA Regulatory Affairs
(913) 268-2588

2. Regulatory Action in Which this Package is Submitted
Data submitted to support the registration of CyLence Ultra Insecticide Cattle Ear Tags (EPA Reg. No. 11556-131; Mr. George LaRocca)

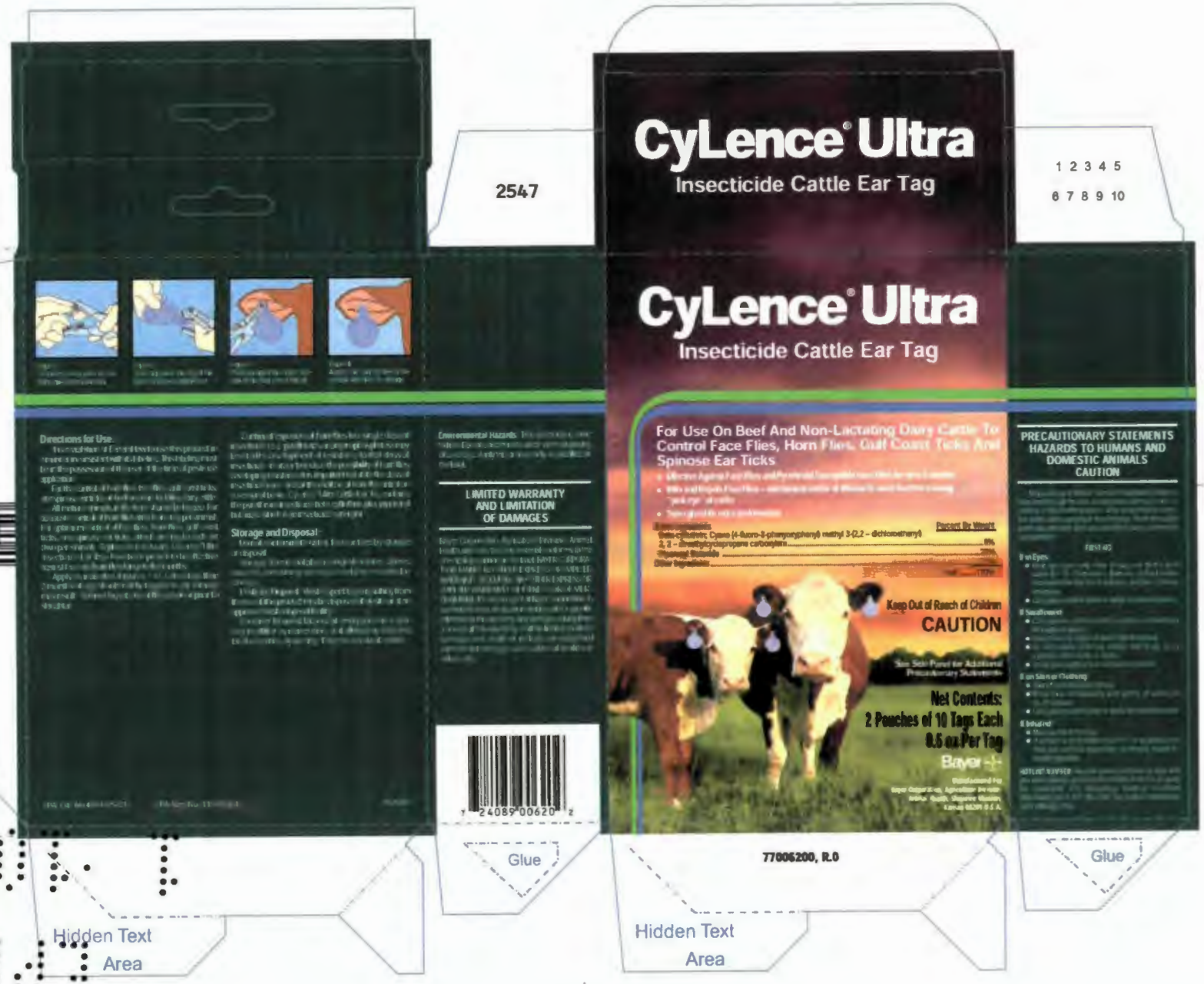
3. Transmittal Date
March 26, 2002

4. List of Submitted Studies:

MRID No.	Volume		
45640701	1	-	"M779 Cattle Ear Tag - An Acute Dermal LD50 Study in the Rat," OPPTS Guideline No. 870.1200, Bayer Report No. 75466, K.L. Johnson, 47 p.

Boehringer
Printed Side
T082901A

Black Cyan Magenta Pantone 3435



NOT REVIEWED
In accordance with PR Notice 8
Based on draft labeling dated
11/2/01

CyLence® Ultra

Insecticide Cattle Ear Tag

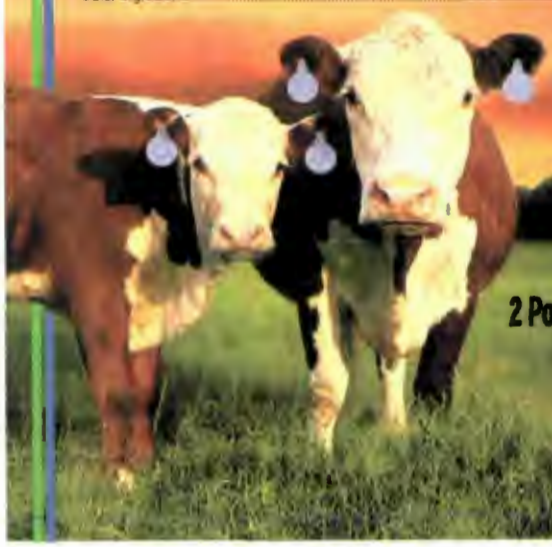
CyLence® Ultra

Insecticide Cattle Ear Tag

For Use On Beef And Non-Lactating Dairy Cattle To Control Face Flies, Horn Flies, Gulf Coast Ticks And Spinose Ear Ticks

- Effective Against Face Flies and Pyrethroid Susceptible Horn Flies for up to 5 months
- Kills and Repels Face Flies – mechanical vector of *Moraxella bovis* bacteria causing "pink eye" of cattle.
- Synergized for extra performance

Active Ingredients	Percent By Weight
Beta-cyfluthrin: Cyano (4-fluoro-3-phenyoxyphenyl) methyl 3-(2,2 – dichloroethenyl) 2, 2 – dimethylcyclopropane carboxylate	8%
Piperonyl Butoxide	20%
Other ingredients:	72%
Total	100%



Keep Out of Reach of Children

CAUTION

See Side Panel for Additional Precautionary Statements

Net Contents:
2 Pouches of 10 Tags Each
0.5 oz Per Tag

Bayer

Manufactured for:
Bayer Corporation, Agriculture Division,
Animal Health, Shawnee Mission,
Kansas 66201 U.S.A.

77006200, R.0

Hidden Text Area

Environmental Hazards: This pesticide is toxic to fish. Do not contaminate water when disposing of used tags. Apply this product only as specified on the label.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, and no agent of Bayer Corporation, is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

7 24089 00620 2

Glue

1 2 3 4 5

6 7 8 9 10

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

May cause eye irritation. Harmful if swallowed, inhaled or absorbed through the skin. Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wear nonpermeable protective gloves when applying or removing tags. Wash thoroughly with soap and water after use and before eating, drinking or using tobacco.

FIRST AID

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15–20 minutes. Remove contact lenses if present after the first 5 minutes, and then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If Swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on Skin or Clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15–20 minutes.
- Call a poison control center or doctor for treatment advice.

If Inhaled:

- Move person to fresh air.
- If person is not breathing call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment information, call 1-877-258-2280. For product information, call 1-800-633-3796.

Glue

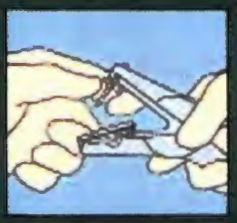


Figure 1
Disinfect pliers prior to use. *Place male button onto pin*

Figure 2
Slide tag under the clip of the *pliers by depressing the lever*

Figure 3
Position tag in the center portion of the front side of the ear

Figure 4
Apply the tag between the second and third rib cartilage

Directions for Use:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in the possession of the user at the time of pesticide application.

For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and non-lactating dairy cattle.

All mature animals in the herd should be tagged. For adequate control of horn flies attach one tag per animal. For optimum control of face flies, horn flies, gulf coast ticks, and spinose ear ticks, attach one tag to each ear (two per animal). Replace as necessary. CyLence® Ultra Insecticide Ear Tags have been proven to be effective against face and horn flies for up to five months.

Apply as indicated (Figures 1-4). Calves less than 3 months of age should not be tagged as ear damage may result. Remove tags at end of fly season or prior to slaughter.

Continual exposure of horn flies to a single class of insecticide (e.g. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance it is important to rotate the class of insecticide used and/or the method of horn fly control on a seasonal basis. CyLence® Ultra Cattle Ear Tag contains the pyrethroid insecticide beta cyfluthrin plus piperonyl butoxide, which is an insecticide synergist.

Storage and Disposal:

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in cool place in original container. Opened pouches containing ear tags should be resealed for storage.

Pesticide Disposal: Waste (spent tags) resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Dispose of empty pouch in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned stay out of smoke.

EPA Est. No.4691-KS-01 EPA Reg. No. 11556-131 062099

Hidden Text Area

Open

CyLence® Ultra

Insecticide Cattle Ear Tag

For Use On Beef And Non-Lactating Dairy Cattle To Control Face Flies, Horn Flies, Gulf Coast Ticks And Spinose Ear Ticks For Up To Five Months.

Active Ingredients	Percent By Weight
Beta-cyfluthrin; Cyano (4-fluoro-3-phenoxyphenyl) methyl 3-(2,2 – dichloroethenyl) 2, 2 – dimethylcyclopropane carboxylate	8%
Piperonyl butoxide	20%
Other Ingredients	72%
Total	100%

EPA Est. No 4691-KS-01 EPA Reg. No. 11556-131

Keep Out Of Reach Of Children

CAUTION

See Box For Precautionary Statements

Net Contents: 10 Tags – 0.5 oz per tag

Bayer

Manufactured For Bayer Corporation, Agriculture Division, *Animal Health, Shawnee Mission, Kansas 66201 U.S.A.*

062099
81006200.R 0

Pg.1

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 11556-131
2. EPA Product Manager: George LaRocca
3. Proposed Classification: ☐ None ☐ Restricted
4. Company/Product (Name): CyLence Ultra Cattle Insecticide Ear Tag
PM#
5. Name and Address of Applicant *(Include ZIP Code)*
Bayer Corporation, Animal Health, Agriculture Division
P.O. Box 390
Shawnee Mission, KS 66201
☐ *Check if this is a new address*
6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☑ Final printed labels in repsonse to Agency letter dated November 2, 2001
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See attached explanation.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* *Certification must submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: ☐ Label ☐ Container
4. Size(s) Retail Container
5. Location of Label Directions: ☐ On Label ☐ On Label accompanying product
6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
F. Terry McNamara	Director, Preclin Dev. and EPA Reg. Affairs	(913) 268-2588

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: F. Terry McNamara
3. Title: Director, Preclinical Development and EPA Reg. Affairs
4. Typed Name: F. Terry McNamara
5. Date: January 7, 2001

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Attachment for Application for Pesticide Registration
CyLence® Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-131

Enclosed with this application are two (2) copies of the final printed label for Bayer's CyLence® Ultra Insecticide Cattle Ear Tag product (EPA Reg. No. 11556-131).

The final label incorporates all of the changes requested by the Agency (EPA letter dated November 2, 2001). Specifically, these changes are:

1) The EPA Registration Number was changed to read "EPA Reg. No. 11556-131".

2) Per PR Notice 97-5, the common name for Beta-cyfluthrin was added to the ingredients statement.

3) Per PR Notice 97-6, "Inert Ingredients" was changed to "Other Ingredients" in the ingredients statement.

4) The following was added to the First Aid Statement:

   HOT LINE NUMBER
   Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment information, call 1-877-258-2280. For product information, call 1-800-633-3796.

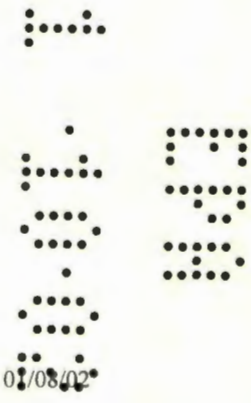
FPL

via 2nd Day Federal Express 01/08/02

George Lamoreaux 1/14/02

Document Processing Desk (APPL)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Enclosure: Application for Pesticide Notification –
CyLence® Ultra Insecticide Cattle Ear Tag
(EPA Reg. No. 11556-131) – with two copies final printed labeling



x:mooij/doc/GGG0052.Doc 01/08/02

via 2nd Day Federal Express 01/08/02

Document Processing Desk (NOTIF)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Enclosure: Application for Pesticide Notification –
CyLence® Ultra Insecticide Cattle Ear Tag
(EPA Reg. No. 11556-131)

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 11556-131

2. EPA Product Manager: George LaRocca

3. Proposed Classification: ☐ None ☐ Restricted

4. Company/Product (Name): CyLence Ultra Cattle Insecticide Ear Tag

PM#

5. Name and Address of Applicant *(Include ZIP Code)*
Bayer Corporation, Animal Health, Agriculture Division
P.O. Box 390
Shawnee Mission, KS 66201

☐ *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☑ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See attached explanation.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: ☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions: ☐ On Label ☐ On Label accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
F. Terry McNamara	Director, Preclin Dev. and EPA Reg. Affairs	(913) 268-2588

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: F. Terry McNamara

3. Title: Director, Preclinical Development and EPA Reg. Affairs

4. Typed Name: F. Terry McNamara

5. Date: January 7, 2001

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

APPLICATION FOR PESTICIDE

Notification of Product Name Change per PR Notice 95-2.

Bayer Corporation, Animal Health is changing the name of its product Cutter Ultra Insecticide Cattle Ear Tag (EPA Reg. No. 11556-131) to CyLence® Ultra Insecticide Cattle Ear Tag.

This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for this product. Bayer understands that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. Bayer further understands that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CRF 152.46, this product may be in violation of FIFRA and Bayer may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION
INSECTICIDE BRANCH

Fax Number (703)-305-6596

FACSIMILE REQUEST/COVER SHEET

SEND FAX TO:

NAME: Terry McNamara

OFFICE: Bayer

FAX PHONE NO.: (913) 268-2541

OFFICE PHONE NO.: (913) 268-2588

FROM:

NAME: Susan Stanton
DIVISION/BRANCH: RD/IB
OFFICE PHONE NO.: (703) 305 - 5218
LOCATION/OFFICE ROOM NO.: Crystal Mall 2 - 1921 Jefferson Davis Hwy., 2nd Floor, Room 222
MAILCODE: (7505C)

DATE: 11/27/01 **TIME:** 10:40

NUMBER OF PAGES (WITH COVER SHEET): 7

SPECIAL MESSAGE -- DESCRIBE BELOW:

Per your request a copy of the DER for the dermal study (EPA Reg No 11556-131) is attached. Let me know if I can be of any further help.

Thanks,

Susan

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:	Date of Issuance:
11556-131	November 2, 2001

Term of Issuance: Conditional

NOTICE OF PESTICIDE:
x Registration
__ Reregistration
(under FIFRA, as amended)

Name of Pesticide Product:
Cutter® Ultra Insecticide Cattle Ear Tag

Name and Address of Registrant (include ZIP Code):

Bayer Corporation, Animal Health, Agriculture Division
P.O. Box 390
Shawnee Mission, KS 66201

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A), provided that you:

1) You will submit the listed data below conducted in accordance with the 40CFR Part 158 Test Guidelines: an acute dermal toxicity study (OECD 402; OPP81-2) no later than March 28, 2002

2) Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of you product under FIFRA section 4.

3) **Make the following labeling changes**:

   a) Revise the EPA Registration Number to read "EPA Reg. No. 11556-131"

   b) Per PR Notice 97-5, please list the common name (in addition to the chemical name) for Beta-cyfluthrin.

Signature of Approving Official:	Date:
Mary Lynkeiguin for George T. LaRocca	November 2, 2001

EPA Form 8570-6

c) Per PR Notice 97-6, please change "Inert Ingredients" to read "Other Ingredients".

d) Please add the following to your First Aid statement:

HOT LINE NUMBER
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

4. Please submit two (2) copies of your final printed label for before your release the product for shipment. Please refer to the A-79 enclosure for a further description of final printed labeling. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

If you have any questions regarding this action, please feel free to contact me (703) 305-6100.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Pouch

CUTTER® ULTRA

INSECTICIDE CATTLE EAR TAG

For use on Beef and Non-Lactating Dairy Cattle to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks for Up to Five Months.

		Percent By Weight
Active Ingredients	Cyano (4-fluoro-3-phenyoxyphenyl) methyl 3-(2,2 – dichloroethenyl) 2, 2 – dimethylcyclopropane carboxylate	8%
	Piperonyl butoxide	20%
Inert Ingredients	. . . . .	72%
Total	. . . . .	100%

ACCEPTED
with COMMENTS
In EPA Letter Dated
November 2, 2001
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 11556-131

Keep Out of Reach of Children

CAUTION

See Box For Precautionary Statements

Net Contents: 10 Tags - 14 g per tag
Manufactured for
Bayer Corporation, Agriculture Division, Animal Health
Shawnee Mission, KS 66201 U.S.A.

EPA Est. No.
EPA Reg. No. 11556-XXX

Box (Front)

CUTTER® ULTRA

INSECTICIDE CATTLE EAR TAG

For use on Beef and Non-Lactating Dairy Cattle to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks

- Effective Against Face Flies and Pyrethroid Susceptible Horn Flies for up to 5 months.
- Kills and Repels Face Flies – mechanical vector of *Moraxella bovis* bacteria causing "pink eye" of cattle
- Synergized for extra performance

		Percent By Weight
Active Ingredients	Cyano (4-fluoro-3-phenyoxyphenyl) methyl 3-(2,2 – dichloroethenyl) 2, 2 – dimethylcyclopropane carboxylate	8%
	Piperonyl Butoxide Technical	20%
Inert Ingredients	. . . . .	72%
Total	. . . . .	100%

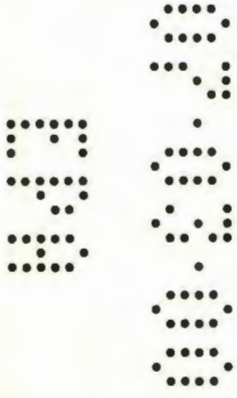
Keep Out of Reach of Children

CAUTION

See Side Panel for Additional Precautionary Statements

Bayer Corporation, Agriculture Division, Animal Health
Shawnee Mission, KS 66201 U.S.A.

Net Contents: 2 pouches of 10 tags each – 14 g per tag



Box (Side Panel)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

May cause eye irritation. Harmful if swallowed, inhaled or absorbed through the skin. Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wear nonpermeable protective gloves when applying or removing tags. Wash thoroughly with soap and water after use and before eating, drinking or using tobacco.

FIRST AID

If in Eyes:
- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present after the first 5 minutes, and then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If Swallowed:
- Call a poison control center or doctor immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin or clothing:
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If Inhaled:
- Move person to fresh air.
- If person is not breathing call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible.

Environmental Hazards: This pesticide is toxic to fish. Do not contaminate water when disposing of used tags. Apply this product only as specified on the label.

Box (Back)

Directions for Use:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in the possession of the user at the time of pesticide application.

For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and non-lactating dairy cattle.

All mature animals in the herd should be tagged. For adequate control of horn flies attach one tag per animal. For optimum control of face flies, horn flies, gulf coast ticks, and spinose ear ticks, attach one tag to each ear (two per animal). Replace as necessary. Cutter® Ultra Insecticide Ear Tags have been proven to be effective against face and horn flies for up to five months.

Apply as indicated (Figures 1-4). Calves less than 3 months of age should not be tagged as ear damage may result. Remove tags at end of fly season or prior to slaughter.

(Illustration)	(Illustration)	(Illustration)	(Illustration)
Figure 1	**Figure 2**	**Figure 3**	**Figure 4**
Disinfect pliers prior to use. Place male button onto pin until it projects through the tip.	Slide tag under the clip of the pliers by depressing the lever.	Position tag in the center portion of the front side of the ear.	Apply the tag between the second and third rib cartilage.

Continual exposure of horn flies to a single class of insecticide (e.g. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance it is important to rotate the class of insecticide used and/or the method of horn fly control on a seasonal basis. Cutter® Ultra Cattle Ear Tag contains the pyrethroid insecticide beta cyfluthrin plus piperonyl butoxide, which is an insecticide synergist.

Storage and Disposal:

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in cool place in original container. Opened pouches containing ear tags should be resealed for storage.

Pesticide Disposal: Waste (spent tags) resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Dispose of empty pouch in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned stay out of smoke.

EPA Est. No.
EPA Reg. No. 11556-XXX

Box (Side Panel)

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, and no agent of Bayer Corporation, is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Bayer Corporation, Agriculture Division, Animal Health
Shawnee Mission, KS 66201 U.S.A.

bc: Reg Book
R. G. Arther
H. Dorn
G. G. Gagliano
R. Hack
F. T. McNamara
D. L. Van Goethem

x:moiij/letters/FTM0301.doc

Bayer

Agriculture Division

Animal Health

Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390
Phone: 913 268-2000

via Federal Express

October 17, 2001

Mr. George T. LaRocca (7505C)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy
Arlington, VA 22202-4501

Subject: Cutter Ultra Cattle Ear Tag, EPA File Symbol 11556-RGR

Dear Mr. LaRocca:

With regard to the subject pending registration, we respectfully request a conditional registration and with this letter provide a commitment to redo the special acute dermal toxicity study for this product. Because of the seasonality of the product (detailed below) we also respectfully request this matter be addressed by the first week of November. We acknowledge and apologize for the urgency of the matter, but as detailed below, we feel you will understand the reasons for a timely resolution. Detailed explanations of these issues are provided below.

History/Background

Bayer Animal Health submitted the initial application for registration for the Cutter Ultra Cattle Insecticide Ear Tag on June 30, 2000. The application passed the administrative screen for completeness and was assigned EPA File Symbol 11556-RGR on July 7, 2000. Bayer received Agency reviews for toxicology (review dated November 6, 2000) and product chemistry (review dated October 17, 2000) on January 9, 2001. The reviews required a change to the Confidential Statement of Formula and special dermal toxicity study.

Historically with Bayer's other ear tags, EPA has not required acute toxicity studies with the ear tags except for the recent Co-Ral Plus tag, EPA Reg No. 11556-123, and in this instance a specially designed dermal toxicity study was required. Bayer's understanding of the need for this special study was that the Co-Ral Plus ear tag contains two acutely toxic organophosphates (coumaphos and diazinon), and data were needed to determine if the combination of these two organophosphates would result in any synergistic acute toxicity. With regard to the pending Cutter Ultra tag registration, as neither betacyfluthrin nor piperonyl butoxide are acutely toxic, (certainly, as with all pyrethroids,

dermal paresthesia was expected and thus Bayer's label includes a requirement for wearing gloves), Bayer did not expect that a special acute dermal toxicity study would be required for this ear tag.

Nevertheless, after receipt of the Agency's January 9, 2001 letter requiring an acute dermal toxicity study, on January 30, 2001, a Bayer toxicologist, Dan Van Goethem, discussed the acute toxicity requirements with John Redden and Tracy Keigwin. It was agreed that only the dermal route was of concern, and the study design could be the same as the one previously developed by John Redden and Dan Van Goethem for Bayer's other cattle ear tag, Co-Ral Plus (EPA Reg. No. 11556-123).

The study for the dermal toxicity study was conducted, and the report sent to the Agency on June 8, 2001. The report was received by the Agency and assigned MRID 45444601 on July 9, 2001.

The revised CSF was submitted to the Agency on June 28, 2001.

As requested by the Agency, Bayer also submitted a formal waiver request for the other five acute toxicity studies for the ear tag on September 5, 2001. These studies are the acute oral toxicity (OPPTS No. 870.1100), inhalation toxicity (OPPTS No. 870.1300), eye irritation (OPPTS No. 870.2400), dermal irritation (OPPTS No. 870.2500) and skin sensitization (OPPTS No. 870.2600) studies.

Bayer's Understanding of the Current Registration Status

It is our understanding that the waiver request and revised Confidential Statement of Formula have been accepted, but the special dermal toxicity will not be accepted by the Agency. Although Bayer does not yet have the review for this study, Bayer will commit to redo the study with any modifications the Agency would want, and Bayer will commit to redo the study and submit the final study report by March 28, 2002 (in approximately 6 months). Bayer acknowledges this commitment to redo a study without the review of the previous study is unusual, but because of the urgency of resolving this matter (reasons detailed below), Bayer is making this commitment for the purpose of obtaining a conditional registration.

Proposal and Justification for Conditional Registration

Bayer respectfully requests that the Agency grant a conditional registration for this product. Completion and submission of a new special dermal toxicity study by March 28, 2002 could be the condition for registration. The length of the conditional registration could be 1 year or whatever length of time the Agency prefers.

With regard to the justification of a conditional registration in this instance, the incremental risk that would result from the conditional registration would be insignificant for the following reasons.

First, the only data not currently available are an acceptable special acute dermal toxicity study. One special acute dermal toxicity study has already been conducted (Bayer Report No. 75303, EPA MRID No. 45444601), but it was determined to be unacceptable. The specific reason(s) the study was deemed unacceptable is not yet known to Bayer, however, our understanding is that the primary concern was that the animals may not have been healthy at the onset of the study. We do not believe this to be the case; nevertheless, we will perform a new study to remove any doubt about the validity of the study. However, if the Agency's primary concern is that the health of the animals was compromised at the onset of the study, the results of the study still provide useful data because the toxicological response to treatment may have been increased, not decreased, due to the use of unhealthy animals. Thus, the results of the study could serve as a worst-case conservative estimate of the acute dermal toxicity of this product and can be used until the results of the new study are available in approximately six months. The study demonstrated that the dermal LD50 of this product was greater than 2000 mg/kg/day corresponding to a Toxicity Category III for dermal toxicity hazard.

Moreover, the findings from the special acute dermal toxicity study on this product are supported by data on the active ingredients in this ear tag, betacyfluthrin and piperonyl butoxide. This product, a hard plastic ear tag, contains approximately 8% betacyfluthrin and 20% piperonyl butoxide. Technical grade betacyfluthrin was found to have a dermal LD50 of greater than 5000 mg/kg (MRID Nos. 412441-05 and 412442-06) and piperonyl butoxide was found to have a dermal LD50 of greater than 2000 mg/kg (*Handbook of Pesticide Toxicology*, 2nd Edition, 2001, Vol. 2, p. 1462). Thus, the data taken collectively provide a high level of confidence that the product has a low order of toxicity by the dermal route and can be used safely while a new study is being performed to address the Agency's concerns with the initial study. Furthermore, the proposed labeling will require the use of gloves which will dramatically reduce dermal exposure to the product.

Second, with regard to the value of the data, the study is designed to assess acute dermal mammalian toxicity and neither betacyfluthrin nor piperonyl butoxide are very toxic to mammals. Furthermore, as previously noted in the Agency's November 6, 2000 assessment for this product, the dermal route is the only route of human exposure. The purpose of this study was to provide data for possible assessment of dermal toxicity to workers handling the tags. The proposed labeling requires the use of gloves which would eliminate or minimize human dermal exposure to this product.

Third, the proposed registration is very similar to the current registration of the Cutter Gold Cattle Insecticide Ear Tag, EPA Reg. No. 11556-106. This is a plastic ear tag containing 10 % cyfluthrin which is obviously very similar to betacyfluthrin. With

regard to piperonyl butoxide, this common synergist is used in many ear tags such as the Cutter Blue Cattle Insecticide Ear Tag, EPA Reg. No. 11556-105. Thus, the proposed registration is similar to products already registered for this use.

Fourth, the cattle ear tag market is a mature, relatively stable, but small, specialized market. Thus the conditional registration will be a niche product for very specialized, experienced users - cattlemen - and clearly has no residential uses.

With regards to the benefits of the Cutter Ultra Cattle Ear Tag, as with all ear tags, it will provide the cattle industry with a very specific, relatively labor free means of long-term insect control for cattle. Apart from other cattle ear tags, the Cutter Ultra tag is particularly effective against face flies and will provide the cattle industry with superior face fly protection in those areas where face flies are problematic.

With regard to the urgency of this request, the market for ear tags is extremely seasonal. Ear tags are only used once a year early in the spring to provide insect control through spring and summer. Thus, sales of ear tags only occur once a year - late in the winter to be available at the distributors in early spring. To have the tags available for the distributor in late winter (and also to allow time to obtain state registrations) the production must occur in mid-winter. Therefore, to have the final packaging/labeling available (labeling, printing takes 6-8 weeks), the final label and registration must be available in late fall (first week of November). If the registration is not available by this time, then the whole sales year is lost. This is the reason for the urgency of this request.

In summary, Bayer commits to conduct a new special dermal toxicity study with the Cutter Ultra Cattle Ear Tag to upgrade the currently available dermal toxicity data. Bayer will provide these data no later than March 28, 2002. Bayer respectfully requests that the Agency grant the conditional registration of this product as the incremental risk that would result from the conditional registration would be insignificant for the reasons detailed above. And lastly, because of the extreme seasonality of this product, Bayer respectfully requests that the Agency provide this in a timely manner.

If you have any questions on this matter, please do not hesitate to contact me at 913-268-2588.

Sincerely,

F. Terry McNamara

F. Terry McNamara
Director,
Preclinical Development and EPA Regulatory Affairs

FTM/lt

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

13/SEPT/2001

MEMORANDUM

Subject:	Name of Pesticide Product:	Cutter Ultra Cattle Insecticide Ear Tag
	EPA Reg. No. /File Symbol:	11556-RGR
	DP Barcode:	D277606
	Case No:	069043
	PC Code:	067501, 128831

From: Eugenia McAndrew, Biologist EM
Technical Review Branch JCR
Registration Division (7505C)

To: Tracy Keigwin, PM Team 03
Insecticide Branch
Registration Division (7505C)

Applicant: Bayer Corporation
Agriculture Division, Animal Health
P.O. Box 390
Shawnee Mission, KS 66201-0390

FORMULATION FROM LABEL:

	Active Ingredient(s):	% by wt.
128831	Cyano (4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl) 2,2-dimethylcyclopropane carboxylate	8
067501	Piperonyl butoxide	20
	Inert Ingredient(s):	72
	Total:	100%

ACTION REQUESTED: Please review dermal toxicity study (MRID # 454446-01) submitted to support registration of Cutter Ultra Cattle Insecticide Ear Tag, EPA File Symbol 11556-RGR.

BACKGROUND: Bayer Corporation has applied for registration of Cutter Ultra Cattle Insecticide Ear Tag, EPA File Symbol 11556-RGR. This product is a cattle ear tag constructed of a plastic impregnated with two active ingredients for use on beef and non-lactating dairy cattle to control face flies, horn flies, gulf coast ticks and spinose ear ticks for up to five months. TRB has addressed the acute toxicity data requirements for this product in memos dated October 26, 2000 and November 6, 2000, in a letter dated January 9, 2001 and in a telephone conversation with the registrant on January 30, 2001. TRB is requiring an acute dermal toxicity study and asked the registrant to provide a rationale for waivers for the other five acute toxicity studies.

The registrant has now submitted an acute dermal toxicity study (MRID # 454446-01). The study was conducted at Bayer Corporation, Agriculture Division, Toxicology, Stilwell, Kansas. The registrant has also submitted the request for waivers for the acute oral, acute inhalation, primary eye irritation, primary skin irritation and dermal sensitization studies.

RECOMMENDATIONS: Waivers may be granted for the acute oral, acute inhalation, primary eye irritation, primary skin irritation and dermal sensitization studies.

The acute dermal toxicity study is classified as unacceptable. TRB has serious concerns that the health of the animals used in the study may have been compromised as evidenced by the unexplained death of one animal in the treated group and by the number of clinical signs such as lacrimal staining, red or brown discharge in the nose and/or eyes, thinning hair around forelimbs and/or eyes, swelling around the neck and thinness seen in the control animals. TRB has reviewed the clarifications on this study submitted by Bayer in a memo dated September 7, 2001 and has concluded that the study is unacceptable because of these preceding discrepancies.

The tentative acute toxicity profile for Cutter Ultra Cattle Insecticide Ear Tag, EPA File Symbol 11556-RGR, is as follows:

acute oral toxicity	IV	Waived	--
acute dermal toxicity	III	Unacceptable	MRID 454446-01
acute inhalation toxicity	IV	Waived	--
primary eye irritation	IV	Waived	--
primary skin irritation	IV	Waived	--
dermal sensitization	IV	Waived	--

TRB has assigned a Toxicity Category of III for the acute dermal toxicity study. TRB has no objection to a conditional registration of EPA File Symbol 11556-RGR (per John Redden, Acute Tox Team Leader and Acting-Branch Chief). The acute dermal toxicity study must be repeated.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System.

ID #: 011556-00131 Cutter Ultra Cattle Insecticide Ear Tag

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

DATA EVALUATION RECORD

STUDY TYPE: ACUTE DERMAL TOXICITY TESTING (870.1200 formerly §81-2)

Product Manager: 03 **Reviewer:** Eugenia McAndrew

TEST MATERIAL (Purity): M779 Cattle Ear Tag; 19.7% Piperonyl Butoxide, 8.3% Beta Cyfluthrin

CITATION: Johnson, K.L. (2001) M779 Cattle Ear Tag; acute dermal toxicity in rats. Bayer Corporation Agriculture Division Toxicology, Stilwell, Kansas. Laboratory Report Number 01-A22-DU. June 1, 2001. MRID 454446-01. Unpublished.

SPONSOR: Bayer Corporation, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201-0390

EXECUTIVE SUMMARY: In an acute dermal toxicity study, six young adult Wistar (Crl: WI(HAN)BR) rats/sex (Weight: 199-224 g males; 169-184 g females; Source: Charles River Laboratories, Inc., Raleigh, NC) were dermally exposed to a single application of M779 Cattle Ear Tag (19.7% Piperonyl Butoxide, 8.3% Beta Cyfluthrin; Batch No. M-98-02-M779-99-02-59; light purple flexible tags) at 2000 mg/kg (limit dose) for 24 hours. A control group of six rats/sex was administered deionized water only. The test article consisted of a piece of the plastic ear tag, M779, moistened with distilled water and applied to > 10% of the total body surface area. Animals were observed for clinical signs of toxicity and mortality at 1, 2 and 4 hours after application and once daily for 14 days.

Dermal LD_{50} Males = > 2000 mg/kg (observed); Dermal LD_{50} Females = > 2000 mg/kg (observed)

Clinical signs observed in the control group include lacrimal staining, red or brown discharge in the nose and/or eyes, thinning hair around forelimbs and/or eyes, swelling around the neck and thinness . Yellow staining in the perigenital area was not considered to be treatment related. In the treated group, one male was found dead on day 1. Clinical signs observed in the treated group include red or brown discharge in the nose and/or eyes, thinning hair around eyes and swelling around the neck. Lesions described as redness or raised zones were noted at the dose sites of 6/11 surviving treated animals. Scabbing was also noted in three females. The animals recovered from all symptoms by day 12. Two males in the treated group lost weight the first week of the study but gained week during the second week. One female in the control group lost weight during the second week. All other animals gained weight during the study. Necropsy results showed bilateral lacrimation in one treated male. The decedent had no treatment related observations.

TRB has serious concerns that the health of the animals used in the study may have been compromised as evidenced by the unexplained death of the one animal in the treated group and by the number of clinical signs such as lacrimal staining, red or brown discharge in the nose and/or eyes, thinning hair around forelimbs and/or eyes, swelling around the neck and thinness seen in the control animals. TRB has reviewed the clarifications on this study submitted by Bayer in a memo dated September 7, 2001and has concluded that the study is unacceptable because of these preceding discrepancies.

This study is classified as Unacceptable (870.1200) and does not satisfy the guideline requirement for an acute dermal study in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
2000	1/6	0/6	1/12

OBSERVATIONS: Clinical signs observed in the control group include lacrimal staining, red or brown discharge in the nose and/or eyes, thinning hair around forelimbs and/or eyes, swelling around the neck and thinness . Yellow staining in the perigenital area was not considered to be treatment related. In the test group, one male was found dead on day 1. Lesions described as redness or raised zones were noted at the dose sites of 6/11 surviving test animals. Scabbing was also noted in three females. The animals recovered from all symptoms by day 12. Two males in the test group lost weight the first week of the study but gained week during the second week. One female in the control group lost weight during the second week. All other animals gained weight during the study. Necropsy results showed bilateral lacrimation in one treated male. The decedent had no treatment related observations.

GROSS NECROPSY: Necropsy results showed bilateral lacrimation in one treated male. The decedent had no treatment related observations.

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D277606
2. **PC CODE:** 067501, 128831
3. **CURRENT DATE:** 13/SEPT/2001
4. **TEST MATERIAL:** M779 Cattle Ear Tag (19.7% Piperonyl Butoxide, 8.3% Beta Cyfluthrin; Batch No. M-98-02-M779-99-02-59; light purple flexible tags)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute dermal toxicity/rat Bayer Corp. Toxicology 01-A22-DU/6-1-01	454446-01	LD_{50} > 2000 mg/kg (males females combined)	III	U

Core Grade Key: **A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated**

George LaRocca 9/12/01

Bayer

Agriculture Division

Animal Health

Bayer Corporation
P O Box 390
Shawnee Mission, KS 66201-0390
Phone: 913 268-2000

Federal Express

September 7, 2001

Mr. George LaRocca
Product Manager
Registration Division (H7505C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Dermal Toxicity Study (MRID 45444601) for Cutter Ultra Cattle Ear Tag
EPA File Symbol 11556-RGR

Dear Mr. LaRocca:

Attached please find some clarification for the dermal acute toxicity study (MRID 45444601) which is currently under review. These comments are provided by Bayer's toxicologist and are based on his recent conversation with the study reviewer. We hope you find them helpful in understanding the scientific validity of the study results.

If you have any questions, please do not hesitate to call me at (913) 268-2588 or Greg Gagliano at (913) 268-2751.

Sincerely,

F. Terry McNamara

F. Terry McNamara
Director, Preclinical Development

FTM:GGG/lt

cc: Tracy Keigwin

Enclosure

Clarification on Clinical Signs Observed in the Study Entitled,
"M779 Cattle Ear Tag, An Acute Dermal LD50 Study in the Rat"
(MRID No. 45444601 and Bayer Toxicology Study No. 01-A22-DU)

Background:

This document was prepared to address issues raised during the Agency's review of the dermal toxicity study (MRID No. 45444601) on Bayer's proposed product, Cutter Ultra Cattle Insecticide Ear Tag. Agency toxicologists, Dr. Masih Hashim, Eugenia McAndrew and John Redden, called Dan Van Goethem of Bayer on September 6th, 2001 to discuss the Agency's review of the study and concerns regarding possible confounding issues with the study.

The issue of most concern was the evidence presented in the report which indicated that the health of the animals may have been compromised at the onset of the study. Serious concern was expressed regarding the numerous clinical signs which were observed in both treated and untreated rats at the first observation period, one hour after treatment, and at subsequent observation periods. Especially disconcerting, were the clinical signs observed in both treated and untreated rats including bloody stains around the eyes and nose and an animal found dead on day 1, approximately 24 hours after treatment. Dr. Hashim suggested that a new study should be performed because it was impossible to interpret the study results due to the compromised health of the animals at the onset of the study.

Dan Van Goethem explained that Bayer evidently had not gone into enough detail in the report to interpret the findings in the context of a study using collars. He discussed the fact that when the Elizabethan collars are used in a study, the red stains are routinely observed because the collars interfere with the normal preening which rodents perform continuously. Dr. Hashim said that he had used the collars in studies up to 90-days in duration and had not observed these types of clinical signs. He suggested that we immediately start a new study since a new study could be completed within a few weeks time, Dan Van Goethem said that he did not know why our experience with collars was different than his unless the design of the collars was different. He requested that before making a final decision on the study, the Agency give Bayer an opportunity to clarify the findings in the study and bring our experiences with the use of collars in other studies into the discussion. The Agency toxicologists agreed to this proposal provided Bayer could provide the clarification by the next day, September 7th. Dan Van Goethem said that he would fax the clarification to the Agency on the 7th (tomorrow).

Clarification:

The Wistar (Crl:WI(HAN)BR) rats used in this study were received from Charles River Laboratories, Inc (Raleigh, NC) and were examined upon receipt (3/12/01) for general appearance and behavior and were found to be normal, healthy animals with no clinical evidence of disease or sickness. Animals were observed twice daily during the acclimation period (3/12/01- 3/18/01) and were found to be normal at every observation period (Attachment I,

Clarification (Contd.):

Room Activity Checklist). The Study Veterinarian, Dr. H. Hoang, examined the animals on 3/19/01 and found no abnormal findings. Thus, Dr. Hoang recommended that the animals be released for the study (Attachment II, *Animal Shipment Examination and Release Form*). It is also important to note that within 1 week of receiving the animal shipment for this study, 610 additional rats were received from the same Charles River facility and animal room. Those animals were all determined to be clinically normal, were used in another study initiated on April 2, 2001, and were never observed with similar clinical signs because EJAY collars were not used in that study.

In the dermal toxicity study with the cattle ear tag, initiation of exposure occurred on March 21, 2001. Just prior to dosing of each individual animal, each was fitted with an Elizabethan collar (EJAY International, Glendora, CA). The collars were intended to reduce animal access to the dose site / wrapping material and thereby prohibit removal of the wrapping material and/or ingestion of the test substance. All animals were collared and dosed between 7:42 and 8:13 A.M. Following completion of the collaring/dosing/wrapping process, detailed clinical observations were made on all study animals, starting at 8:48 A.M. The only signs observed at that time were as follows:

	Within Normal Limits	Dark Red Discharge (both eyes)
Male:	Control - 4/6 Treated - 6/6	Control - 2/6 Treated - 0/6
Female:	Control - 5/6 Treated - 6/6	Control - 1/6 Treated - 0/6

(Attachment III, *Clinical Observations Daily Listing*). The discharges observed in the present study correlate with normally-occurring secretions of the mouth, nose, eye, and harderian gland and are commonly associated with the use of the EJAY collar, with most of the initial collar-related signs occurring shortly after collaring. The harderian gland secretes several products, one consists primarily of lipids (wax esters) and the other product produced by the glandular cells is porphyrin. The secretions are red in color due to the porphyrin and are quite pronounced against the white hair on the collared albino rats. Similar signs have been noted in other studies utilizing the same collars, most of which resolve following collar removal (Attachment IV, Sheets, 1996). Moreover, in a two-year rat study utilizing the EJAY collar, initial collar-related signs progressed to more severe signs over time; however, as in the shorter term studies, most signs had disappeared following collar removal (Attachment V, Wahle, et al., 1999). Gross pathological examination of the animal which died and all other study animals revealed no evidence of disease or sickness. Unexplainable incidental deaths occasionally occur in groups of clinically and gross pathologically healthy animals. Stress from the collar and wrapping of the torso may have caused the death of the animal found dead on day 1, but there is no way to know for certain. Most importantly, neither this animal nor any of the other treated animals ever displayed any clinical sign of pyrethroid intoxication.

Clarification (Contd.):

Conclusions:

The clinical observational tables currently included in the report may give the impression that animals used in the study were exhibiting clinical signs prior to study initiation; however, as described above, all animals used on the study were normal prior to study start. Moreover, clinical signs commonly noted with the use of EJAY Elizabethan collars did not appear until animals had been collared. The data from the in-life observations and examinations from the time of receipt of the animals to the time of necropsy, and the data from the gross pathological examinations clearly demonstrate that the health of the animals was not compromised at any time prior to or during the study.

We believe the study to be scientifically sound and to provide reliable data from which to assess the dermal toxicity hazard of the cattle ear tag. This product contains only 8.14% beta-cyfluthrin incorporated into a plastic matrix, so very little is bioavailable. The dermal LD_{50} and systemic NOEL of greater that 2000 mg/kg, which was determined in this study, is consistent with the findings of studies on technical grade beta cyfluthrin which was found to have a dermal LD_{50} of greater than 5000 mg/kg (MRID Nos. 412441-05 and 412442-06). Thus, the active ingredient is poorly absorbed through the skin, resulting in a very low order of acute toxicity via the dermal route.

We request the Agency's concurrence that with the clarification provided herein, this study fulfills the requirements for an acceptable acute dermal toxicity study.

K. L. Johnson — Date: 09/07/01
Study Director

B. S. Wahle — Date: 9/7/01
Rodent Studies

D. L. Van Goethem — Date: 9/7/01
Veterinary Stewardship and Canine/Feline Studies

Attachment I

Room Activity Checklist

ROOM ACTI...TY CHECKLIST FROM: MARCH 12,2001 TO: MARCH 18, 2001 (B) ROOM: 307

	MON	TUE	WED	THR	FRI	SAT	SUN
DATE	12	13	14	15	16	17	18
AM - ANIMALS OBSERVED NORMAL	AB, KSP	AB	AB	AB	KSP	RK JDJ	RK JDJ
PM - ANIMALS OBSERVED NORMAL	AB	AB	AB	AB	AB, KSP	RK JDJ	RK JDJ
FEEDING/FEED CHECK	AB, KSP	AB	AB	AB	KSP	RK JDJ	RK JDJ
FEEDERS CHANGED							
BEDDING: DACB			AB		KSP		
BEDDING: BED-O-COBS							
BEDDING: LITTER			AB BD				
ROOM SWEPT	AB		AB		KSP		
MOPPED ROOM WITH QAC			AB		KSP		
INSTALLED CLEAN MOP HEAD					KSP		
CLEAN RACKS/BEDDING 1446	OES						
CLEAN RACKS/BEDDING							
RACK CHANGE COMPLETE							
ASR DISINFECTED USING QAC							
DOG CAGES FLUSHED & FLOOR DISINFECTED W/QAC							
DOG CAGES, FLOOR AND ROOM DISINFECTED W/QAC							
EXERCISED DOGS AT LEAST 15 MINUTES							
STRAHMAN M-6000 USED							
FILTERS: 1 ✓ CHANGED 1 X CHECKED	AB X		AB ✓				
CLEAN FLOOR GRATES EXCHANGED							
FELINE FLOORING EXCHANGED 1 1SWEPT1 1							
LITTER PANS& RESTING SURFACES EXCHANGED							
Corridors cleaned							
RACK CHECK NORMAL 1 ✓ ROOM EMPTY 1 1						RK JDJ	RK JDJ
SHIPMENT RECEIVED/CAGE CARDS PLACED AB, KSP 3/12/01			MALES 2		FEMALES 2	RANDOMIZED	

DATE:	COMMENTS:	DATE:	COMMENTS:

TOX FORM 189 (Rev 12/00) QAC=Quaternary Ammonium Compound ASR=Animal Study Room

Blk ens. AB 3/14/01
(B) entry error 4/17/01 RK

UNDERSTOOD BY/DATE REM 3/26/01

Attachment II

Animal Shipment Examination and Release Form

ANIMAL SHIPMENT EXAMINATION AND RELEASE FORM

REQUEST NUMBER 2045 STUDY NUMBER 01-A22-DU Acute Dermal Tox (LD50)

ROOM NUMBER 307 COMPOUND Cutter gold ear tag

RECEIVED DATE 3/12/01

	MALES	FEMALES
CAGE CARD START NUMBER	1	1
BIRTH DATE...( )Approximate (X)Calculated	1-22-01	1-22-01
NUMBER RECEIVED	21	21
EXTRA (if any)	Included in total Received →	

SPECIES Strain and/or Substrain

X Rattus norvegicus ___ Sprague-Dawley ___ Fischer 344 X Wistar Han

___ Mus musculus ___ CD1

___ Canis familiaris/Beagle

___ Other ___

SOURCE

X Charles River Laboratories, Inc., ___ Kingston, NY ___ Portage, MI X Raleigh, NC ___ Hollister, CA ___ Margate, Kent, U.K.

___ White Eagle Laboratories, Doylestown, PA ___ Other ___

TRANSPORTATION X Vendor Vehicle ___ Air Express ___ Other ___

RANDOMIZATION BY ___ Animal Care Personnel Using SAS Software Random Number List

X Study Personnel at a later date

DESCRIPTION OF EXAMINATION X No Abnormal Findings Noted

___ Abnormal Findings are Listed Below:

COMMENTS: ___

SHIPMENT EXAMINATION BY AB, KSP DATE 3/12/01

EXPERIMENTAL ANIMAL SPECIALIST [signature] DATE 3-12-01

RELEASED DATE 3-19-01 NUMBER RELEASED....MALES 21 ...FEMALES 21

Based on the data shown on Tox Form 189 / 02 and my examination noted above, I recommend that these animals

✓ BE ACCEPTED ___ NOT BE ACCEPTED For the above procedures or study.

VETERINARIAN [signature] DATE 3-19-01

EXPERIMENTAL ANIMAL SPECIALIST [signature] DATE 3-19-01

UNDERSTOOD BY STUDY DIRECTOR [signature] DATE 03/19/01

TOX FORM 407 Revised 11/99 White - EAS, Yellow - Study Director, Pink - DVM, Goldenrod - Path. Admin.

Attachment III

M779 Cattle Ear Tag:
An Acute Dermal LD50 Study in the Rat

Clinical Observational Daily Listing For Study Day 0
(March 21, 2001)

OBSERVATIONS DAILY LISTING

DATE 21-MAR-01 TYPE CLINICAL

GROUP A DOSE control

ANIMAL NO.	OPR ID	OBVN DAY	TIME	OBSERVATION	
DU0001					
	KLJ	0	8:48	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:31	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:43	DISCHARGE EYES-BOTH	DARK RED
DU0002					
	KLJ	0	8:48	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:31	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:43	DISCHARGE EYES-BOTH	DARK RED
DU0003					
	KLJ	0	8:48	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:32	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:44	GENOBS	WITHIN NORMAL LIMITS.
DU0004					
	KLJ	0	8:49	DISCHARGE EYES-BOTH	DARK RED
	KLJ	0	10:33	DISCHARGE EYES-BOTH	DARK RED
	KLJ	0	11:45	DISCHARGE NOSE	DARK RED
DU0005					
	KLJ	0	8:50	DISCHARGE EYES-BOTH	DARK RED
	KLJ	0	8:50	DISCHARGE NOSE	DARK RED
	KLJ	0	11:45	DISCHARGE NOSE	DARK RED
	KLJ	0	11:45	DISCHARGE EYES-BOTH	DARK RED
DU0006					
	KLJ	0	8:50	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:34	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:46	GENOBS	WITHIN NORMAL LIMITS.

OBSERVATIONS DAILY LISTING

DATE 21-MAR-01 TYPE CLINICAL

GROUP B DOSE limit dose

ANIMAL NO.	OPR ID	OBVN DAY	TIME	OBSERVATION	
DU1001					
	KLJ	0	8:51	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:34	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:47	DISCHARGE EYES-BOTH	DARK RED
DU1002					
	KLJ	0	8:51	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:35	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:47	DISCHARGE EYE-RIGHT	DARK RED
DU1003					
	KLJ	0	8:51	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:35	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:48	GENOBS	WITHIN NORMAL LIMITS.
DU1004					
	KLJ	0	8:52	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:36	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:48	GENOBS	WITHIN NORMAL LIMITS.
DU1005					
	KLJ	0	8:52	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:36	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:49	GENOBS	WITHIN NORMAL LIMITS.
DU1006					
	KLJ	0	8:53	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:36	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:49	GENOBS	WITHIN NORMAL LIMITS.

OBSERVATIONS DAILY LISTING

DATE 21-MAR-01 TYPE CLINICAL

GROUP A DOSE control

ANIMAL NO.	OPR ID	OBVN DAY	TIME	OBSERVATION	
DU0101					
	KLJ	0	8:58	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:37	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:49	DISCHARGE EYES-BOTH	DARK RED
DU0102					
	KLJ	0	8:58	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:38	DISCHARGE EYES-BOTH	BRIGHT RED
	KLJ	0	11:50	DISCHARGE EYES-BOTH	BRIGHT RED
	KLJ	0	11:50	DISCHARGE NOSE	BRIGHT RED
DU0103					
	KLJ	0	8:58	DISCHARGE EYES-BOTH	DARK RED
	KLJ	0	10:39	DISCHARGE EYES-BOTH	DARK RED
	KLJ	0	11:51	DISCHARGE EYES-BOTH	DARK RED
DU0104					
	KLJ	0	8:59	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:40	DISCHARGE EYES-BOTH	BRIGHT RED
	KLJ	0	11:52	DISCHARGE EYES-BOTH	BRIGHT RED
DU0105					
	KLJ	0	8:59	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:40	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:52	GENOBS	WITHIN NORMAL LIMITS.
DU0106					
	KLJ	0	9:00	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:41	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:53	DISCHARGE EYES-BOTH	DARK RED

O B S E R V A T I O N S D A I L Y L I S T I N G

DATE 21-MAR-01 TYPE CLINICAL

GROUP B DOSE limit dose

ANIMAL NO.	OPR ID	OBVN DAY	TIME	OBSERVATION	
DU1101					
	KLJ	0	9:03	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:41	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:53	DISCHARGE EYES-BOTH	DARK RED
	KLJ	0	11:53	DISCHARGE NOSE	DARK RED
DU1102					
	KLJ	0	9:04	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:42	DISCHARGE NOSE	BRIGHT RED
	KLJ	0	11:54	DISCHARGE NOSE	BRIGHT RED
	KLJ	0	11:54	DISCHARGE EYES-BOTH	BRIGHT RED
DU1103					
	KLJ	0	9:05	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:42	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:54	DISCHARGE EYES-BOTH	DARK RED
DU1104					
	KLJ	0	9:06	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:43	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:55	GENOBS	WITHIN NORMAL LIMITS.
DU1105					
	KLJ	0	9:11	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:43	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	11:56	DISCHARGE EYES-BOTH	DARK RED
	KLJ	0	11:56	DISCHARGE NOSE	DARK RED
DU1106					
	KLJ	0	9:11	GENOBS	WITHIN NORMAL LIMITS.
	KLJ	0	10:43	DISCHARGE EYES-BOTH	BRIGHT RED

O B S E R V A T I O N S D A I L Y L I S T I N G

DATE 21-MAR-01 TYPE CLINICAL

GROUP B DOSE limit dose

ANIMAL NO.	OPR ID	OBVN DAY	TIME	OBSERVATION	
	KLJ	0	11:56	DISCHARGE EYES-BOTH	BRIGHT RED
	KLJ	0	11:56	DISCHARGE NOSE	BRIGHT RED

END OF OBSERVATIONS DAILY LISTING REPORT

Attachment IV

Sheets, L.P. (1996). A repeated dose 90-day dermal toxicity study with technical grade KBR 3023 in rats. Unpublished report No. 107047 (MRID 44408716), Bayer Corporation, Agriculture Division, Kansas City, MO.

(Pages 1, 21, 22, and 30)

107047

Study Title

A Repeated Dose 90-Day Dermal Toxicity Study
with Technical Grade KBR 3023 in Rats

Data Requirement

40 CFR Part 158
US-EPA-FIFRA, Section 158.340, Guideline 82-3

Author

L. P. Sheets

Author, Pathology Report

S. G. Lake

Study Completion Date

November 1, 1995

Test Facility

Bayer Corporation
Agriculture Division
Toxicology
17745 South Metcalf
Stilwell, Kansas 66085-9104

Study Number

90-122-HC

Page 1 of 710

RESULTS AND DISCUSSION

Animal Care

The Animal Care Report is provided in Section B of the Pathology Report (page 141). There were no excursions from the defined ranges in temperature or relative humidity during the study.

Analysis of Feed and Water

The results for feed were compared to the allowable limits in "Lab Chows Animal Diet Reference Guide" (Publication SP2437M-87010 dated 1987) from Ralston Purina Co., St. Louis, MO. No contaminant levels measured in the batches of Rodent Laboratory Chow used in this study were considered to have affected the outcome of this study.

No contaminant levels were found in water samples that were considered to affect the outcome of this study.

Clinical Observations and Mortality

Clinical observations are summarized in Table 1 (page 30) and the corresponding individual data are tabulated in Appendix III (page 41). The criteria for scoring irritation are presented in Appendix II (page 40). Dermal irritation results are summarized in Table 2 (page 34) and individual animal results are presented in Appendix IV (page 86). The results for individual animals are only shown for females through day 26 of exposure since irritation was not evident in males on any occasion and was not apparent in females on later occasions.

There were no deaths prior to the scheduled terminal sacrifice.

The appearance of males and females that received dosages of 500 or 1000 mg/kg/day indicated that the test substance spread to cover an area that extended well beyond the dose site. At the 1000 mg/kg dose level, the hair lateral to the dose site, on the sides and across the shoulders of the animals, appeared to be moistened with the test substance. Thus, a much larger area of skin was exposed, affording the opportunity for more extensive absorption of the dose than if the exposure had been limited to 10% of the body surface area. In addition, the dose spread to areas where the rats could ingest the dose through grooming, affording the opportunity for even greater exposure. To a lesser extent, rats in the lower dose groups also had spreading of the test substance beyond the area of the dose site. After 24 hours, when it was time to administer the next dose, there was no evidence that the test substance remained on the surface of the skin; however, the hair of animals in the high-dose group still had the appearance of being moistened with the test substance. Based on these findings, it is expected that exposure to dosages of 500 and 1000 mg/kg/day exceeded 10% of the body surface area and included oral as well as dermal exposure.

Clinical signs that are considered to be treatment-related were limited to lesions at the dose site. This included scabs and red foci that were evident in all groups of males and females that received the test substance, with the incidence generally increasing with dose and appearing later at the lowest dose level. These effects resolved in all recovery group animals by 16 days after the cessation of treatment. The development of exfoliation and an orange "cast" or hue to the dose site that were noted during the study are also considered to represent compound-related effects (results not shown). Exfoliation was observed at the dose site of all males and all females that received the test substance. This condition became apparent around day 7, persisted through the end of exposure, and resolved in all high-dose recovery animals within 12 days after treatment was discontinued. The development of an orange hue to the treated skin occurred in all females that received the test substance, beginning around day 11. As discussed below, the development of this color may have interfered with the observation of erythema at the dose site.

During the first three or four weeks of treatment, some females in each dose group that received the test substance developed erythema at the dose site as evidence of irritation (Table 2, page 34). During week 2 of exposure, this consisted of a dose-related increase in the incidence of grade 1 (very slight) erythema in a total of 0, 2, 4 and 8 females that received dosages of 80, 200, 500 and 1000 mg/kg/day, respectively. Erythema developed as early as day 1 at the high dose, appeared later at lower dose levels, and resolved in most animals by day 17. As mentioned previously, the observation of this very slight redness was confounded by the development of an orange "cast" or hue at the dose site. This color may have represented an accumulation of epidermal cells and secretions that would normally slough from the skin, in combination with the clear test substance. Signs of irritation were not apparent in any female after week 4 and were not apparent in males at any time.

Most of the remaining clinical observations were ascribed to the wearing of the Elizabethan collars for a prolonged period. These observations are considered to have resulted from either the physical contact between the collar and the animal or to the collars interfering with the animal's ability to groom themselves. These effects consisted of stains on the head (nose, eyes and mouth) and body; lacrimation and eye irritation; scabs, sores and alopecia on the head, neck and body; evidence of inflammation involving the penis and urethra; and a swollen digit and forefoot. Two days after removal of the collars (day 96), all but two of these signs had resolved in the satellite animals. Scabs around the neck of four recovery animals resolved by day 112 and alopecia around the neck of all recovery animals was still present on the day of sacrifice.

The presence of rales in one high-dose male on day 48 appeared to occur at random and is not considered to be related to either treatment or the collars.

Table 1

Summary of Clinical Observations for Rats Treated with Technical Grade KBR 3023 in a 90-Day Dermal Toxicity Study

MALES

Sign	Dosage (mg/kg/day) 0	0 (recovery)		80	200	500	1000	1000 (recovery)	
	0-94[a]	0-88[a]	89-119[b]	0-94[a]	0-94[a]	0-94[a]	0-94[a]	0-88[a]	89-119[b]
DOSE SITE									
Scabs	-[c]	-	-	2/54-74[d]	5/5-89	6/3-94	8/6-92	5/4-88	1/89-98
Red Foci	-	-	-	1/25	3/17-25	4/17-38	5/16-47	5/18-25	-
HEAD AND NECK									
Red Nasal Stain	10/0-94	10/0-88	10/89-94	10/0-94	10/0-94	10/0-94	10/0-94	10/0-88	7/89-94
Yellow Nasal Stain	4/9-92	6/6-84	3/89-94	8/2-94	8/2-92	9/8-93	10/5-92	9/2-88	6/89-94
Red Lacrimal Stain	4/0-78	9/0-87	2/90-94	8/0-84	6/0-93	7/0-93	6/0-82	7/0-82	-
Eye Irritation	1/45	6/1-88	2/89-92	2/46-88	5/0-91	2/2-92	3/1-87	3/44-54	1/89-92
Yellow Stain on Eyelid(s)	-	1/10-45	-	1/11	2/5-31	4/1-47	5/5-50	4/6-37	-
Alopecia Around Eyes[f]	5/0-30	8/0-30	-	5/0-30	5/0-30	2/0-30	6/0-30	6/0-30	-
Scabs on Lip	-	-	-	1/74-75	-	-	-	-	-
Perioral Alopecia, Scabs, Edema and White Stain	-	-	1/90-106[g]	-	-	-	-	-	-
Scabs on Neck	6/3-90	8/3-88	6/89-108	5/3-92	6/1-94	8/0-92	4/1-92	3/0-82	3/92-112
Sore on Neck	-	-	-	1/80-81	-	-	-	-	-

a Treatment interval in days.
b Recovery period in days; all collars were removed prior to observation on day 95.
c Sign not observed.
d Incidence with 10 rats per dose/time range of occurrence (in days; usually intermittent, not continuous).
e Result of one animal catching a toenail on the Velcro of the collar.
f After day 30-31, the alopecia was minimal or not evident and was no longer recorded as a clinical observation. Appendix III lists this sign for individual animals as alopecia under the heading acute observations.
g Result of one animal catching incisors in the wire mesh of his cage.

Attachment V

Wahle, B.S., Sangha, G.K., Lake, S.G., Sheets, L.P., Croutch, C., and Christenson, W.R. (1999). Chronic toxicity and carcinogenicity testing in the Sprague-Dawley rat of a prospective insect repellant (KBR 3023) using the dermal route of exposure. *Toxicology* **142**, 41-56.

ELSEVIER

Toxicology 142 (1999) 41–56

TOXICOLOGY

www.elsevier.com/locate/toxicol

Chronic toxicity and carcinogenicity testing in the Sprague–Dawley rat of a prospective insect repellant (KBR 3023) using the dermal route of exposure☆

Bradley S. Wahle, Ghona K. Sangha, Stephen G. Lake, Larry P. Sheets, Claire Croutch, Ware R. Christenson *

Agriculture Division, Toxicology, Bayer Corporation, 17745 South Metcalf, Stilwell, KS 66085-9104, USA

Received 12 July 1999; accepted 1 September 1999

Abstract

The chronic toxicology and carcinogenic potential of 1-(1-methyl-propoxycarbonyl)-2-(2-hydroxyethyl)-piperidine (KBR 3023), a prospective new insect repellent intended for human use, was studied in rats using the dermal route of application. Relying upon the toxicology profile that emerged in the subchronic rat bioassay that was conducted using dermally applied dosages of 0, 80, 200, 500 and 1000 mg KBR 3023/kg body wt/day, it was determined, in concert with the Environmental Protection Agency (EPA), that dermally applied dosages of 0, 50, 100 or 200 mg KBR 3023/kg body wt/day would be used in the conduction of all definitive forms of subchronic, chronic, and lifetime descriptive testing performed with the chemical. Using this testing approach, the specific results of this 2-year study are as follows. All in-life parameters, which included body weight, food consumption, clinical observations, survival, ophthalmology, clinical chemistry, hematology, and urinalysis, were unaffected by exposure to KBR 3023. Similarly, postmortem analyses, which included organ weights and gross pathology, were also unchanged following exposure to KBR 3023. Histopathology at the dose site/skin was characterized by a pattern of acanthosis and/or hyperkeratosis across all doses in 1- and 2-year rats. Beyond the dosing site, cystic degeneration of the liver was described in 2-year 200-mg KBR 3023/kg body wt/day males. No other compound-related non-dosing site lesion was identified at any dose tested. No evidence of a compound-induced neoplasia was suggested in this bioassay.

Keywords: KBR 3023; Insect repellant; Dermal toxicity testing; Risk assessment

Abbreviations: AAALAC, American Association for Accreditation of Laboratory Animal Care; CAS, Chemical Abstract Services; EPA, Environmental Protection Agency; NOEL, no-observed-effect-level; wt, weight.

☆ *Portions of this work were presented at the annual meeting of the Society of Toxicology, Seattle, WA, March 1–5, 1998.*

* Corresponding author. Tel.: +1-913-433-5225; fax: +1-913-433-5125.

E-mail address: russ.christenson.b@bayer.com (W.R. Christenson)

0300-483X/99/$ - see front matter

PII: S0300-483X(99)00129-8

Bayer

Federal Express

Agriculture Division

Animal Health

Bayer Corporation
P.O. Box 390
Shawnee Mission KS 66201 0390
Phone 913 268-2000

June 8, 2001

Mr. George LaRocca
Product Manager
Registration Division (H7505C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Application for Registration for Cutter Ultra Cattle Ear Tag
EPA File Symbol 11556-RGR

Dear Mr. LaRocca:

Enclosed with this cover letter is a report transmittal form and three copies of the study report entitled, "M779 Cattle Ear Tag – An Acute Dermal LD_{50} Study in the Rat" (Bayer Report No. 75303). The purpose of this cover letter is to provide a brief, explanatory overview of the submission which may aid in the processing of the application.

The report is being sent in response to the Agency's letter dated January 9, 2001 (attached). EPA requested dermal toxicity data for Bayer's new cattle ear tag (active ingredients beta cyfluthrin and piperonyl butoxide). This is a non-standard study, therefore Bayer's toxicologist discussed the study design with EPA's toxicologist and registrations reviewer to reach agreement prior to initiating the study (see attached Bayer letter and telephone conversation minutes dated February 21, 2001).

If you have any questions, please do not hesitate to call me at (913) 268-2588 or Greg Gagliano at (913) 268-2751.

Sincerely,

F. Terry McNamara
Director, Preclinical Development

FTM:GGG/lt

Enclosures

cc: Tracy Lynn Keigwin (7505C)

Transmittal Document

1. Name and Address of Submitter

Bayer Corporation
Agriculture Division
Animal Health
Box 390
Shawnee Mission, Kansas 66201-0390

F. Terry McNamara

F. Terry McNamara
Manager, Preclinical Development
(913) 268-2588

2. Regulatory Action in Which this Package is Submitted

Data submitted to support registration for Cutter Ultra Cattle Ear Tag, EPA File Symbol 11556-RGR (active ingredients – beta cyfluthrin and piperonyl butoxide; Mr. George LaRocca)

3. Transmittal Date

June 8, 2001

4. List of Submitted Studies:

MRID No.	Volume	
~~REJECT~~ 45444601	1	- "M779 Cattle Ear Tag – An Acute Dermal LD_{50} Study in the Rat," EPA Guideline No. 870.1200, Bayer Report No. 75303, K.L. Johnson, 46 p.

DATE OUT: 06/SEP/2001

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [ ] End-Use Product [X]
DP BARCODE: D277609 **RECEIVED DATE:**29/JUN/2001 **FILE SYMBOL/REG.No** 11556-RGR
PRODUCT NAME: Cutter Ultra Insecticide Cattle Ear Tag **MRID.:** None
COMPANY NAME: Bayer Corporation **ACTION CODE:** 166

FROM: Sami Malak, Chemist
Technical Review Branch/RD (7505C)

TO: 03 Arnold Layne/Tracy Keigwin
Insecticide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 28/JUN/2001, the applicant responded to EPA's letter of 09/JAN/2001 reflecting a product chemistry memorandum and submitted a revised product's CSF, a basic formulation dated 28/JUN/2001 (S. Malak, DP #267613, 17/OCT/2000).

FINDINGS:

1. The applicant addressed deficiency 5(b) in our previous memorandum and cited the registration number of one of two technical sources in the submitted revised CSF, a basic formulation dated 28/JUN/2001 (S. Malak, DP #267613, 17/OCT/2000).

2. Except for the resolved data gap in Finding 1 above, the applicant had previously satisfied product chemistry data requirements for a FIFRA sec. 3(c)(5) registration of subject product. Product's label was also accepted in our previous memorandum.

CONCLUSIONS:

The submitted revised product's CSF, a basic formulation dated 28/JUN/2001, is acceptable. The applicant has satisfied product chemistry requirements for a FIFRA sec. 3(c)(5) registration of subject product.

cc:S. Malak and Central File (Reg. No.11556-RGR).
7505C:RD:TRB:CM-2:268:s.m.:06/SEP/2001:703-308-9365:<11556RGR>.

Bayer

Agriculture Division

Animal Health

Bayer Corporation
P O Box 390
Shawnee Mission, KS 66201-0390
Phone: 913 268-2000

George LaRocca 7/2/01

Via Federal Express

June 28, 2001

Mr. George LaRocca
Product Manager
Registration Division (H7505C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Application for Registration for Cutter Ultra Cattle Ear Tag
EPA File Symbol 11556-RGR

Dear Mr. LaRocca:

Enclosed with this cover letter is an Application for Pesticide Registration and two copies of the Confidential Statement of Formula (CSF) for the above referenced product. The purpose of this cover letter is to provide a brief, explanatory overview of the submission which may aid in the processing of the application.

The CSF is being sent in response to the Agency's letter dated January 9, 2001 (attached). EPA requested some slight changes to the CSF, namely, the address for the supplier of each inert (including the common "commodity" chemicals) and the addition of the EPA Registration Number for the active ingredient, beta-cyfluthrin. The enclosed CSF is the last piece of information required by the Agency for registration of this product.

I hope this overview cover letter is helpful in processing the attached application. If you have any questions, please do not hesitate to call me at (913) 268-2588 or Greg Gagliano at (913) 268-2751.

Sincerely,

F. Terry McNamara

F. Terry McNamara
Director, Preclinical Development

FTM:GGG/lt

Enclosures

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [x] **Registration**
- [ ] **Amendment**
- [ ] **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 11556-RGR

2. EPA Product Manager: George LaRocca

3. Proposed Classification: [x] None [ ] Restricted

4. Company/Product (Name): Cutter Ultra Cattle Insecticide Ear Tag

PM#

5. Name and Address of Applicant *(Include ZIP Code)*
Bayer Corporation, Animal Health, Agriculture Division
P.O. Box 390
Shawnee Mission, KS 66201

[ ] *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [x] Resubmission in response to Agency letter dated 1/9/01
- [ ] Notification - Explain below.
- [ ] Final printed labels in reponse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

The attached CSF has been revised as per EPA request to include the EPA Reg. No. for the active ingredient beta-cyfluthrin, and the names and addresses for all listed ingredients.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistent Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [ ] Label [ ] Container

4. Size(s) Retail Container

5. Location of Label Directions: [ ] On Label [ ] On Label accompanying product

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
F. Terry McNamara	Director, Preclinical Development	(913) 268-2588

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: for FTM

3. Title: Director, Preclinical Development

4. Typed Name: F. Terry McNamara

5. Date: June 28, 2001

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

George LaRocca 9/10/01

Bayer

Agriculture Division

Animal Health

Bayer Corporation
P O Box 390
Shawnee Mission, KS 66201-0390
Phone 913 268-2000

Federal Express

September 5, 2001

Mr. George LaRocca
Product Manager
Registration Division (H7505C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Application for Registration for Cutter Ultra Cattle Ear Tag
EPA File Symbol 11556-RGR

Dear Mr. LaRocca:

As recommended in your January 9, 2001 letter, Bayer conducted an acute dermal toxicity study on our proposed new product, Cutter Ultra Cattle Insecticide Ear Tag (EPA File Symbol 11556-RGR). The study is currently in the Registration Division for review, and per the Agency's request, this is a formal request for a waiver of the other five acute toxicity studies on the ear tag. These studies are the acute oral toxicity (OPPTS No. 870.1100), inhalation toxicity (OPPTS No. 870.1300), eye irritation (OPPTS No. 870.2400), dermal irritation (OPPTS No. 870.2500) and skin sensitization (OPPTS No. 870.2600) studies.

In Bayer's June 30, 2000 submission for registration, Bayer related how the physical nature of the proposed product - a plastic ear tag - is not a practical test article for the conduct of the usual battery of acute toxicity studies. In the Agency's January 9, 2001 letter, the Agency (in addition to advising Bayer to request a waiver for the other five acute studies) related that "We are requesting an acute dermal toxicity study because this seems the only route of human exposure. However, depending on the results of the acute dermal toxicity study, all or part of the remaining acute studies may be required."

We concur with the Agency's assessment that the dermal route is the only route of human exposure. We have conducted and submitted a report (MRID No. 45444601) on the acute dermal toxicity study. This study demonstrated that this product does not pose an acute dermal toxicity hazard to workers who attach this product to the ears of cattle. This study was performed in accordance to a study design/protocol discussed and agreed upon in a January 30, 2001 telephone conference between Bayer's toxicologist, Dan Van Goethem, the Agency's toxicologist, John Redden, and the Product Manager, Tracy Keigwin. The

dermal LD_{50} and the systemic NOEL was determined to be greater than 2000 mg/kg. Thus, this product has a very low order of acute toxicity via the dermal route. These findings are consistent with the results of acute dermal toxicity studies with technical grade beta-cyfluthrin (MRID Nos. 412441-05 and 412442-06); in both studies the LD_{50} values were greater than or equal to 5000 mg/kg/day in male and female rats. Moreover, the proposed label for this product requires that workers wear protective gloves when handling this product. Thus, if dermal exposure does occur, it would be at negligible levels.

With regard to the other five acute toxicity studies, they are not warranted based on the results of the acute dermal toxicity study and other factors. First, this product is not a residential product and will only be used by adults handling cattle to punch the ears and insert the tags. Acute oral toxicity and eye irritation is not of concern because this product is a large (2.5 x 3.5 inch), hard plastic ear tag, which could not be swallowed and will not enter the eye. This product does not present an inhalation hazard to workers since no aerosolization or vaporization of this product will occur when used as intended. Beta-cyfluthrin has an extremely low vapor pressure, 7.2×10^{-9} mm Hg at 20 degrees Celsius and, therefore, is not prone to volatilization. The active ingredient is minimally irritating to skin (Toxicity Category IV) and is not a dermal sensitizer.

In summary, based on physical form of the product, the intended use, the low exposure potential, the negligible dermal toxicity hazard and the amount of data available for the active ingredient, additional acute toxicity studies are not necessary. Furthermore the use of animals for additional toxicity studies is not warranted. Thus, based on the data, taken collectively, we request a waiver of the requirements for acute oral, inhalation, eye irritation, dermal irritation and dermal sensitization studies on this product.

If you have any questions, please do not hesitate to call me at (913) 268-2588 or Greg Gagliano at (913) 268-2751.

Sincerely,

F. Terry McNamara

F. Terry McNamara
Director, Preclinical Development

FTM:GGG/lt

cc: Tracy Keigwin

George Latrace 2/26/01

Bayer

Via Federal Express

Agriculture Division

Animal Health

Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390
Phone: 913 268 2000

February 21, 2001

Ms. Tracy Lynn Keigwin
Office of Pesticide Programs, 7505C
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Subject: Response to Product Chemistry and Toxicology Reviews
EPA File Symbol 11556-RGR

Dear Ms. Keigwin:

This letter serves as Bayer's response as per your letter dated January 9, 2001 regarding additional requirements for the new product registration application for Cutter Ultra Insecticide Cattle Ear Tag (EPA File Symbol 11556-RGR).

Regarding the Agency's requirement for a special acute dermal toxicity study, Bayer agrees to conduct such a study. On January 30, 2001 Bayer's toxicologist, Dan Van Goethem, discussed the experimental design with EPA's toxicology reviewer, John Redden (see attached telephone conversation minutes). The study design will be exactly the same as the acute dermal toxicity study performed for another Bayer cattle ear tag product (Cutter 2X, EPA Reg. No. 11556-123). Upon completion, the final report for the study will be submitted to the Agency for review.

Regarding the Agency's request for changes to the Confidential Statement of Formula, the active ingredient (beta cyfluthrin) was registered after the initial application for 11556-RGR was submitted to EPA. Under separate cover Bayer will provide a revised CSF which will include the EPA Registration Number for beta cyfluthrin.

Please call me at 913-268-2588 or Mr. Greg Gagliano at 913-268-2751 if you have any questions or need additional information.

greg.gagliano.b@Bayer.com

Sincerely,

F. Terry McNamara

F. Terry McNamara
Manager, Preclinical Development

FTM:GGG/lt

Attachment

cc: John Redden, 7505C

Telephone Conversation Minutes

Date: January 30, 2001

Participants: Dan Van Goethem – Bayer Corporation
John Redden – EPA-OPP
Tracy Keigwin – EPA-OPP

Subject: Dermal Toxicity Study
Cutter Ultra Cattle Insecticide Ear Tag (EPA File Symbol 11556-RGR)

As a follow-up to US EPA's January 9, 2001 letter concerning our new product registration application for Cutter Ultra Cattle Insecticide Ear Tag (EPA File Symbol 11556-RGR), John Redden, the reviewing toxicologist, Tracy Keigwin, the product manager, and I discussed the data requirements over the phone.

John was familiar with the beta-cyfluthrin toxicology database because over 10 years ago he had reviewed Bayer's application for registration of this product. He said he remembered that it was more toxic than cyfluthrin and that in Bayer's application for registration of the new ear tag, only acute toxicity data for cyfluthrin were cited. Thus, he was not comfortable with bridging especially for the acute dermal toxicity study. I told John that the resolved isomer mixture, beta-cyfluthrin, was approximately 2-fold more toxic than cyfluthrin via the oral route, but not by the dermal route. I also mentioned that both beta-cyfluthrin and cyfluthrin were poorly absorbed via the skin as evidenced by acute dermal LD_{50} values of greater than 5000 mg/kg for each product. Furthermore, I stated that the proposed draft label required users to wear pesticide-resistant gloves. John said this was good information to know, but since this was a new product with no similar product containing beta-cyfluthrin and piperonyl butoxide to bridge from, at least a dermal LD_{50} study should be performed.

We then discussed and it was agreed that the study design could be the same as the design for the study he and I had previously developed for dermal toxicity testing of the Coumaphos/Diazinon Cattle Insecticide Ear Tag (EPA Reg. No. 11556-123). John and Tracy said that a very short Agency review time for the final report for this proposed study would be possible. John said he was almost certain that the Agency would not require any other studies if this study demonstrated no toxicity or a very low order of toxicity. John suggested that in our transmittal letter accompanying the submission of the final report for the proposed study, we mention the agreements reached in this discussion. Also, to further allay potential Agency concerns, he also suggested we mention the use of gloves and the fact the technical grade beta-cyfluthrin has a very low order of acute dermal toxicity.

At the conclusion of the discussion, I volunteered to write a call report of our discussion and send it to the Agency via Greg Gagliano in our Registration's Group. Tracy and John agreed that this was the best way to document our discussion and enter it into the Agency's records.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 9, 2001

Mr. F. Terry McNamara
Bayer Corporation, Animal Health, Agriculture Division
P.O. Box 390
Shawnee Mission, KS 66201

Subject: New Product Registration
Cutter Ultra Cattle Insecticide Ear Tag
EPA Reg. Nos. 11556-RGR
Your Application Dated June 30, 2000

Dear Mr. McNamara:

The application for registration of the subject product is not acceptable for the reasons given below. When the requested information is submitted further consideration will be given to this application and your proposed labeling will be evaluated thoroughly.

The product you are claiming similarity to for toxicological purposes does not contain the same active ingredients as those of your product. Your product is composed of Beta Cyfluthrin and Piperonyl Butoxide. The product you have cited only contains cyfluthrin. You will need to cite a different product which not only contains the same active ingredients but contains them at the same or a higher concentration. Alternatively you may do an Acute dermal toxicity study (OECD 402; OPP 81-2) on your product and request a waiver for the other five acutes. The waiver requests should contain sufficient scientific rationale addressing possible human exposure. We are requesting an acute dermal toxicity study because this seems the only route of human exposure. However, depending on the results of the Acute dermal toxicity study all or part of the remaining acute studies may be required.

With regard to your chemistry data, it was not clear if you wish to register the Beta cyfluthrin technical. If not, please list on your CSF carry over impurities associated with

this source, each identified by chemical name, CAS registry number, nominal concentration and upper certified limit. Nominal concentrations can be listed between parenthesis in column 13 (b) of the CSF, not to be included in the material balance of 100%.

Please respond within 75 days from the date of this letter stating your intentions to comply with the information/data requests cited above. If no resubmission is received during the 75-day period, the application will be administratively withdrawn. If you have any further questions regarding this action, please contact Tracy Keigwin of my team at (703) 305-6605.

Sincerely,

Tracy Lynn Keigwin

George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

06/November/2000
MEMORANDUM

Subject: Addendum to Cutter Ultra Cattle Insecticide Ear Tag
EPA Reg. No.: 11556-RGR
DP Barcode: D267614
Case No: 069043
PC Code: 067501 piperonyl butoxide
128831 Cyfluthrin

From: John C. Redden, Team Leader
Technical Review Branch
Registration Division (7505C)

To: Tracy Keigwin
Insecticide Branch
Registration Division (7505C)

Applicant: Bayer Corporation
Agriculture Division, Animal Health
P.O. Box 390
Shawnee Mission, KS 66201-0390

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.

Cyano (4-fluro-e-phenyoxyphenyl)methyl 3-(2,2-dichloroethenyl) 2,2 - dimethylcyclopropane carboxylate.....	8%
Piperonyl butoxide.....	20%
Inert Ingredient(s):	72%
Total:	100%

ACTION:

The reviewer requested the wrong study in the previous review.

CONCLUSION:

TRB mistakenly requested the dermal irritation study. The corrected final paragraph of the previous memorandum appears below:

> "As the product is a plastic cattle ear tag, as an alternative, the Registrant may do an Acute dermal toxicity study (OECD 402; OPP 81-2) and request a waiver for the other five acutes. The waiver requests should contain sufficient scientific rationale addressing possible human exposure. TRB is requesting the Acute dermal toxicity study, because this seems the only possible route of human exposure. However, depending on the results of the Acute dermal toxicity study all or part of the remaining acute studies may be required."

DATE OUT: 17/OCT/2000

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [ ] End-Use Product [X]
DP BARCODE: D267613 RECEIVED DATE:03/JUL/2000 FILE SYMBOL/REG.No 11556-RGR
PRODUCT NAME: Cutter Ultra Insecticide Cattle Ear Tag **MRID.:** 451597-01
COMPANY NAME: Bayer Corporation **ACTION CODE:** 165

FROM: Sami Malak, Chemist
Technical Review Branch/RD (7505C)

TO: 03 Arnold Layne/Tracy Keigwin
Insecticide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 30/JUN/2000, the applicant requested a FIFRA sec. 3(c)(5) registration of subject product. In support of this action, the applicant included product chemistry data, product's label EPA received 03/JUL/2000, a basic formulation, CSF dated 30/JUN/2000, Formulator's Exemption Statement, Data Matrix, and an authorization letter from the Crop Protection Group of Bayer Corporation to permit the Agency access to the generic data on beta cyfluthrin. The applicant is claiming the selective method of support.

FINDINGS:

1a. The subject product, a solid insecticide, is intended for use in cattle ear tag of beef and non-lactating dairy cattle, a plastic matrix ear tag impregnated with the active ingredients.

1b. The product is produced by an integrated formulation system, meaning that one of the two technical sources in the product is not registered. The product contains 8% of a non-registered Beta cyfluthrin technical: Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)2,2-dimethylcyclopropanecarboxylate plus 20% Piperonyl butoxide, [redacted].

2. The submitted/referenced product chemistry data is adequate and support a FIFRA sec. 3(c)(5) registration of subject product.

3. Adequate analytical method is available for enforcement. Adequate analytical method is available for enforcement. ECTO Method No. 019, Report No. M779R03, Study No. M779S03, is included in MRID #751549-03 page 22. In this method, the ear tag is dissolved in an internal standard solution. An aliquot is then diluted acetonitrile and Beta cyfluthrin and piperonly butoxide are quantitated by gas chromatography equipped with flame ionization detector. Method validation data, accuracy and precision are adequate. Sample calculation and chromtaograms are included with this submission.

4. The label claim nominal concentration of 8% Beta cyfluthrin technical plus 20% Piperonyl

butoxide is consistent with that on the CSF, both are in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement is in compliance with the regulations of 40CFR§156.10. No physical or chemical hazards are anticipated from the subject product.

5a. The submitted product's basic, CSF dated 30/JUN/2000, was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed on the CSF are cleared for use in pesticide formulations.

5b. It was not clear if the applicant wishes to register Beta cyfluthrin technical. If not, the applicant should be advised to list on subject product's basic CSF carry over impurities associated with this source, each identified by chemical name, CAS registry number, nominal concentration and upper certified limit. Nominal concentrations can be listed between parenthesis in column 13(b) of the CSF, not to be included in the material balance of 100%.

CONCLUSIONS:

After resolving Finding 5(b) above, we will have no objections for a FIFRA sec. 3(c)(5) registration of subject product. Product's label is acceptable as per Finding 4 above.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 28/DEC/1999 was included with this submission claiming confidentiality of some of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI data is to be found in Confidential Appendix A.

2. A GLP statement dated 20/DEC/1999 was included with this submission to the effect that some of the submitted studies were conducted in compliance with GLP requirements of 40CFR§160.

DATA SUBMITTED

MRID #451597-01 The submitted study entitled: "Report For Chemistry Evaluation of M779 Cattle Ear Tags containing 8% beta cyfluthrin and 20% piperonyl butoxide, Data Requirement of Guideline Reference Numbers Section 61, 62 and 63." The studies were authored by J. E. Rose; Performed by Ecto Development Corporation of Excelsior Springs, MO; Completed on 20/DEC/1999 (31 pages).

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

830-1550 Product Identity and Composition

This product contains two technical grade of active ingredients, one registered and a second non-registered source plus cleared inert ingredients (refer to product's CSF, dated 20/JUN/2000).

830-1600 Description of Materials Used to Produce the Product:
Refer to Confidential appendix A.

830-1650 Description of Formulation Process:
Refer to Confidential appendix A.

830-1670 Discussion of Formation of Impurities:
Refer to Confidential appendix A.

830-1700 Preliminary Analysis:
Refer to Confidential appendix A.

830-1750 Certified Limits:
Refer to Confidential appendix A.

830-1800 Enforcement Analytical Method:

Adequate analytical method is available for enforcement. ECTO Method No. 019, Report No. M779R03, Study No. M779S03, is included in MRID #751549-03 page 22. In this method, the ear tag is dissolved in an internal standard solution. An aliquot is then diluted acetonitrile and Beta cyfluthrin and piperonly butoxide are quantitated by gas chromatography equipped with flame ionization detector.

Method validation data, accuracy and precision are adequate. Sample calculation and chromtaograms are included with this submission.

GC Parameters were reported as follows:

Instrument	H/P 5890 or equivalent
Column	30 meter 0.53 mm DB-17, 1 micron film thickness
Initial Oven Temperature	210 C (hold or 2 minutes)
Final Oven Temperature	260 C
Temperature ramp	7 C/minute
Injection Temperature	275 °C
Detector Temperature	300 °C
Injection Volume	1μl
Run Time	25 minutes
Carrier gas	Helium

Carrier gas flow rate 20 ml/minute
FID gasses Hydrogen and air
FID gas flow rate Adjust to opposite flame and signal

Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190):

GRN 830-/TITLE	VALUE OR QUALITATIVE DESCRIPTION
-6302 Color	Purple
-6303 Physical State	Solid
-6304 Odor	Plastic odor
-6314 Oxidation/Reduction: Incompatibility	Will not act as an oxidizing or reducing agent.
-6315 Flammability/Flame Extension	NA
-6316 Explodability	NA
-6317 Storage Stability	NA as per PR Notice 92-5.
-6319 Miscibility	NA
-6320 Corrosion Characteristics	Non corrosive.
-6321 Dielectric Breakdown Voltage	Not recommended for use around electrical equipment.
-7000 pH	NA
-7100 Viscosity	NA
-7300 Density/Relative Density Bulk Density	1.337 (specific gravity)

Confidential Appendix A

830-1600 Description of Materials Used to Produce the Product:

This product contains two technical grade of active ingredients, one registered and a second non-registered plus cleared inert ingredients (refer to product's CSF, dated 20/JUN/2000).

830-1650 Description of Formulation Process:

This product was formulated using a mixture of one registered and a second non-registered technical grade of active ingredients plus cleared inert ingredients (refer to product's CSF dated 30/JUN/2000). In the process, [redacted]

830-1670 Discussion of Formation of Impurities:

The applicant reported no impurities ≥1% by weight were known to be formed during formulation and storage of the product.

830-1700 Preliminary Analysis:

Will be required if Beta cyfluthrin is not registered.

830-1750 Certified Limits:

The applicant reported the same ingredients at percentages and low/upper limits as those reported on product's CSF.

cc:S. Malak and Central File (Reg. No.11556-RGR).
7505C:RD:TRB:CM-2:268:s.m.:17/OCT/2000:703-308-9365:<11556RGR>.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

26/October/2000
MEMORANDUM

Subject: Cutter Ultra Cattle Insecticide Ear Tag
EPA Reg. No.: 11556-RGR
DP Barcode: D267614
Case No: 069043
PC Code: 067501 piperonyl butoxide
128831 Cyfluthrin

From: John C. Redden, Team Leader
Technical Review Branch
Registration Division (7505C)

JCR

To: Tracy Keigwin
Insecticide Branch
Registration Division (7505C)

Applicant: Bayer Corporation
Agriculture Division, Animal Health
P.O. Box 390
Shawnee Mission, KS 66201-0390

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Cyano (4-fluro-e-phenyoxyphenyl)methyl 3-(2,2-dichloroethenyl) 2,2 - dimethylcyclopropane carboxylate	8%
Piperonyl butoxide	20%
Inert Ingredient(s):	72%
Total:	100%

ACTION:

The PM's instructions:

> "They are citing the precautionary labeling of EPA Reg. No. 11556-106, but they have also cited on their matrix EPA Reg. Nos. 3125-289 (which was a product that was never registered and was a DDVP product to boot! They have cited this reg# for 3 of the 6 acute studies!)...Can they cite different products for the 6 pack and precautionary labeling?"

BACKGROUND:

This product is a cattle ear tag, constructed of a plastic impregnated with two active ingredients. The cyfluthrin is actually Beta Cyfluthrin, which is "an enhanced isomer ratio primarily consisting of the biologically active isomers of Cyfluthrin." The Registrant is claiming substantial similarity to EPA Reg. No. 11556-106, which contains Cyfluthrin not Beta Cyfluthrin. It is TRB's understanding that the enhanced isomer ratio of Beta Cyfluthrin may make it more toxic to humans. However, even if TRB ignores this difference EPA Reg. No. 11556-106 only contains one of the actives in the proposed product.

The Registrant does not cite any products in support of acute toxicity studies for the second active ingredient, Piperonyl butoxide. The Agency normally requires a registered product, containing both active ingredients, for a claim of substantially similarity.

Internal guidance entitled, "Standard Operating Procedure for Substantially Similar Products," offers the following guidance:

- The proposed product has active ingredient(s) (a.i.) which are present (identical PC Codes) in the cited product. Their percentages in the proposed product cannot be greater than in the cited product.

- Similarity is determined by citing a single registered product. This means

that TRB will not consider cases in which the registrant cites more than one registered product attempting to demonstrate substantially similarity. In general, a substantially similarity determination is done by comparing a proposed product to a registered product, which contains all actives, with well-defined acute toxicity categories (ideally, one with a complete six-pack).

CONCLUSION:

Clearly, the Registrant did not meet the standard in this submission. The cited product is not substantially similar to the proposed product. The Registrant needs to cite a product that contains both the actives that are in the proposed product. Also, the concentration in the cited product for both actives should be equivalent or greater than the concentration in the cited product.

As the product is a plastic cattle ear tag, as an alternative, the Registrant may do an Acute dermal irritation study (OECD 404; OPP 81-5) and request a waiver for the other five acutes. The waiver requests should contain sufficient scientific rationale addressing possible human exposure. TRB is requesting the dermal irritation study, because this seems the only possible route of human exposure. However, depending on the results of the dermal irritation study all or part of the remaining acute studies may be required.

3

Bayer

Agriculture Division

Crop Protection Products

Bayer Corporation
8400 Hawthorn Road
P.O. Box 4913
Kansas City, MO 64120-0013
Phone: 816 242-2000

June 23, 2000

Mr. George LaRocca
Registration Division (H7504C)
Office of Pesticide Programs
U.S. ENVIRONMENTAL PROTECTION AGENCY
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

SUBJECT: Use of Bayer Corporation Research and Test Data

Dear Mr. LaRocca:

Bayer Corporation, Agriculture Division, hereby authorizes the Agency to refer to the Bayer research and test data for Beta-Cyfluthrin, in support of the registration of products containing the active ingredient **Beta-Cyfluthrin**, submitted by **Bayer Animal Health**, Company Number 11556.

Cutter Ultra Insecticide Ear Tag
11556-XXX RGR 2

This authorization is granted only to the applicant named above for the product registrations described. This authorization may not be transferred by the applicant named above in any manner whatsoever without the express prior consent of Bayer Corporation. All Information contained in our confidential ingredients statement or otherwise claimed as being confidential or proprietary may not be released to the applicant without the express prior consent of Bayer Corporation.

Bayer Corporation hereby waives the 30-day notification period prior to registration of this application as provided for in 40 CFR 152, Subpart E, Section 152.116(c).

Sincerely,

Charles W. Boyd

Charles W. Boyd
Senior Registration Scientist
Research and Development

/cwb
cc: Gregg Gagliano
P.O. Box 390
Shawnee Mission, Kansas 66210

Attachment for Application for Pesticide Registration –
Cutter Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-~~xxx~~ RGR

With this application, the enclosed data and the enclosed labeling, Bayer Corporation requests the registration of Cutter Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-xxx. Five copies of the proposed labeling, dated 6/22/2000, are enclosed.

Briefly, this product will consist of a plastic matrix ear tag impregnated with active ingredients. Two (2) re-sealable foil pouches, each containing ten (10) ear tags, will be placed in a cardboard box. The foil pouch inside the box will contain only the draft labeling indicated on page 1 of the label text, dated 6/22/2000. The cardboard box will contain all of the draft labeling text (pages 2 – 5 of the enclosed draft labeling, dated 6/22/2000). Also note, this packaging and labeling scheme is identical to that used by Bayer's currently registered ear tag products, Cutter Blue Insecticide Cattle Ear Tag (EPA Reg. No. 11556-105) and Cutter Gold Insecticide Cattle Ear Tag (EPA Reg. No. 11556-106).

Please note, the proposed product is a cattle ear tag containing two already registered active ingredients – piperonyl butoxide and cyfluthrin. Piperonyl butoxide is registered in many, many products including ear tags such as Bayer's Cutter Blue Insecticide Cattle Ear Tag, EPA Reg. No. 11556-105. Cyfluthrin is also registered in many, many products including ear tags such as Bayer's Cutter Gold Insecticide Cattle Ear Tag, EPA Reg. No. 11556-106. Whereas this already registered ear tag contains 10% cyfluthrin, the new proposed ear tag will contain 8% beta cyfluthrin.

Beta cyfluthrin contains a single active ingredient, cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate at 98% by weight. This product is substantially similar to Baythroid® Technical Insecticide (EPA Reg. No. 3125-356). The difference is that Tempo® Ultra Technical is comprised of Beta-Cyfluthrin; an enhanced isomer ratio primarily consisting of the biologically active isomers of Cyfluthrin.

PRODUCT CHEMISTRY

The insecticide formulation is a plastic matrix which contains the active ingredients. Two (2) copies of the Confidential Statement of Formula (CSF) for this product are enclosed. The product chemistry data to support the registration of this new formulation are in the following Bayer Report:

> Bayer Report No. 75142 entitled "The Chemistry Evaluation of 'M779 Cattle Ear Tags' (containing 8% Beta Cyfluthrin and 20% Piperonyl Butoxide)"

Three (3) copies of this report accompany this application. Although the report titles do not use the "Cutter Ultra" trade name, the formulation described and tested is Cutter Ultra Insecticide Cattle Ear Tag.

ACUTE TOXICITY

The acute toxicity studies normally associated with a new formulation were not conducted because they are not practical or necessary for the ear tag. In explanation, the physical nature of the proposed product, which is a plastic ear tag, is not a practical test article for the conduct of the "6-pack" toxicity studies (Guideline 81-1 through 81-6). Acute toxicity studies were not conducted for the Cutter Gold (10% cyfluthrin) Insecticide Cattle Ear Tags (EPA Reg. No. 11556-106) and these ear tags have been used for approximately 10 years.

The precautionary label language in the enclosed draft labeling is based upon the precautionary label language on the 10% cyfluthrin ear tag (EPA Reg. No. 11556-106) and the Agency's recent PR Notice 2000-3 regarding first aid statements. Please note the statement, "Wear nonpermeable protective gloves when applying or removing tags" has been added to the Hazards to Humans and Domestic Animals Section.

RESIDUE CHEMISTRY

No residue chemistry are provided with this application as none are necessary. In explanation, both active ingredients are already registered for many uses including cattle ear tags at equivalent or higher levels of active ingredients. Among the many ear tags with piperonyl butoxide, Python Insecticide Cattle Ear Tags (EPA Reg. No. 39039-4) contain 20% piperonyl butoxide. With regard to cyfluthrin, Bayer's Cutter Gold Insecticide Cattle Ear Tag (EPA Reg. No. 11556-106) contains 10% cyfluthrin.

EFFICACY

As provided for in the regulations, Bayer requests that the requirements for efficacy be waived.

DATA COMPENSATION

An appropriate data matrix listing all of the data necessary to support the registration of Cutter Ultra Insecticide Cattle Ear Tag is enclosed with this application. Please note, the enclosed data matrix cites only those data necessary for this registration. This registration application is for a product used only on cattle (classified as an indoor use); the data matrix does not cite any beta cyfluthrin environmental fate, ecological effects nor crop residue chemistry data because these data are not necessary for this proposed registration.

Generic Data

The Crop Protection group of Bayer Corporation's Agriculture Division is the basic registrant of beta cyfluthrin, therefore, the Animal Health group cannot claim Formulator's Exemption for the generic data requirements. Accordingly, enclosed is a copy of Letter of Authorization from the Crop Protection group (EPA Company No. 3125) of the Agriculture Division authorizing the use of the generic beta cyfluthrin data by the Animal Health group (EPA Company No. 11556) of the Agriculture Division. These generic data are cited in the enclosed data matrix.

A completed Formulator's Exemption Form is enclosed to cite generic data for piperonyl butoxide.

Product Specific Data

All of the data necessary to support the registration of Cutter Ultra Insecticide Cattle Ear Tag are data previously submitted by Bayer's Animal Health group (EPA Company No. 11556) or are enclosed with this application. All of these data are cited in the enclosed data matrix.

As demonstrated in the enclosed, completed Certification With Respect to Citation of Data (EPA Form 8570-29), we are choosing the Selective Method of Support for beta cyfluthrin data. Again, a Letter of Authorization from Bayer's Crop Protection group (EPA Company No. 3125) to cite these data is enclosed.

CHILD RESISTANT PACKAGING

Certification that the packaging for Cutter Ultra Insecticide Cattle Ear Tag meets the child-resistant packaging standards in 40 CFR 157.32 is not necessary because Cutter Ultra does not meet any of the toxicity criterion listed in 40 CFR 157.22 (a) for products requiring child resistant packaging.

NFT

B

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [x] Registration
- [ ] Amendment
- [ ] Other

OPP Identifier Number: 263960

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
11556-~~xxx~~ RGR	George LaRocca	[x] None [ ] Restricted
4. Company/Product (Name) Cutter Ultra Cattle Insecticide Ear Tag	**PM#** 03	

5. Name and Address of Applicant *(Include ZIP Code)*
Bayer Corporation, Animal Health, Agriculture Division
P.O. Box 390
Shawnee Mission, KS 66201

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [x] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See Attachment

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [x] Paper [ ] Other (Specify) _____
* Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	Box containing 20 ear tags	[x] On Label [ ] On Label accompanying product

6. Manner in Which Label is Affixed to Product [x] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
F. Terry McNamara	Manager, Preclinical Development	(913) 268-2588

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received
F. Terry McNamara	Manager, Preclinical Development	(Stamped)
4. Typed Name F. Terry McNamara	**5. Date** June 30, 2000	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
263960

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	

5. Name and Address of Applicant *(Include ZIP Code)*

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No		☐ Yes ☐ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
*rtification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	8. Date Application Received (Stamped)
4. Typed Name	5. Date	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
263960

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	

5. Name and Address of Applicant *(Include ZIP Code)*

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
[illegible]rtification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

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1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

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1-5. Self-explanatory.
6. EPA Use Only.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

07/05/00

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Bayer Corporation, Animal Health, Agriculture Division
P.O. Box 390
Shawnee Mission, KS 66201

PRODUCT NAME: Cutter Ultra Cattle Insecticide Ear Tag
COMPANY NAME: Bayer Corporation, Animal Health, Agriculture Division
OPP INDENTIFICATION NUMBER: 263960
EPA FILE SYMBOL: 11556-RGR
EPA RECEIPT DATE: 07/03/2000

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The Office of Pesticides Programs has received your application for a new registration and it has passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

If you have any questions, please contact the Insecticide Branch, at (703)-305-5200.

Sincerely,

Front End Processing Staff
Information Resources & Services Division
Information Services Branch

Bayer

Agriculture Division

Crop Protection Products

Bayer Corporation
8400 Hawthorn Road
P.O. Box 4913
Kansas City, MO 64120-0013
Phone: 816 242-2000

June 22, 2000

Mr. George LaRocca
Registration Division (H7504C)
Office of Pesticide Programs
U.S. ENVIRONMENTAL PROTECTION AGENCY
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

SUBJECT: Use of Bayer Corporation Research and Test Data

Dear Mr. LaRocca:

Bayer Corporation, Agriculture Division, hereby authorizes the Agency to refer to the Bayer research and test data for Beta-Cyfluthrin, in support of the registration of products containing the active ingredient **Beta-Cyfluthrin**, submitted by **Bayer Animal Health**, Company Number 11556.

Cutter Ultra Insecticide Ear Tag
11556-~~XXX~~ RGR

This authorization is granted only to the applicant named above for the product registrations described. This authorization may not be transferred by the applicant named above in any manner whatsoever without the express prior consent of Bayer Corporation. All Information contained in our confidential ingredients statement or otherwise claimed as being confidential or proprietary may not be released to the applicant without the express prior consent of Bayer Corporation.

Bayer Corporation hereby waives the 30-day notification period prior to registration of this application as provided for in 40 CFR 152, Subpart E, Section 152.116(c).

Sincerely,

Charles W. Boyd

Charles W. Boyd
Senior Registration Scientist
Research and Development

/cwb
attachment
cc: Gregg Gadliano
P.O. Box 390
Shawnee Mission, Kansas 66210

Transmittal Document

1. Name and Address of Submitter

Bayer Corporation
Agriculture Division
Animal Health
Box 390
Shawnee Mission, Kansas 66201-0390

F. Terry McNamara

F. Terry McNamara
Manager, Preclinical Development
(913) 268-2588

2. Regulatory Action in Which this Package is Submitted

Data submitted to support the registration of Cutter Ultra Insecticide Cattle Ear Tag (EPA File Symbol 11556-~~ane~~ RGR; Mr. George LaRocca)

3. Transmittal Date

June 30, 2000

4. List of Submitted Studies:

MRID No.	Volume	
	1	- "The Chemistry Evaluation of 8% Beta Cyfluthrin + 20% Piperonyl Butoxide Ear Tags for Cattle," EPA Guideline Sections 61, 62 and 63, Bayer Report No. 75142, J. E. Rose, 29 p.

Transmittal Document

1. Name and Address of Submitter
Bayer Corporation
Agriculture Division
Animal Health
Box 390
Shawnee Mission, Kansas 66201-0390

F. Terry McNamara

F. Terry McNamara
Manager, Preclinical Development
(913) 268-2588

2. Regulatory Action in Which this Package is Submitted
Data submitted to support the registration of Cutter Ultra Insecticide Cattle Ear Tag (EPA File Symbol 11556-~~xxx~~ RGR; Mr. George LaRocca)

3. Transmittal Date
June 30, 2000

4. List of Submitted Studies:

MRID No.	Volume	
	1	- "The Chemistry Evaluation of 8% Beta Cyfluthrin + 20% Piperonyl Butoxide Ear Tags for Cattle," EPA Guideline Sections 61, 62 and 63, Bayer Report No. 75142, J. E. Rose, 29 p.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Bayer Corporation, Animal Health, Agriculture Division P.O. Box 390 Shawnee Mission, KS 66201	11556-~~xxx~~ BCR 131
Active Ingredient(s) and/or representative test compound(s): Beta-cyfluthrin	Date: June 30, 2000
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158): Indoor	Product Name: Cutter Ultra Cattle Insecticide Ear Tag

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
F. Terry McNamara	June 30, 2000	F. Terry McNamara Mgr, Preclinical Development

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

07-03-00

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date June 30, 2000				EPA Reg No./File Symbol 11556-~~xxx~~ RGR		Page 1 of 11
Applicant's/Registrant's Name & Address	Bayer Corporation Agriculture Division, Animal Health P.O. Box 390 Shawnee Mission, KS 66201			Product Cutter® Ultra Insecticide Cattle Ear Tag		
Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
Section 158.190	PRODUCT CHEMISTRY					
61-1	Identity of ingredients	41205710 44648201	3125 3125 11556		PER PER OWN	Brochure 1628 (TGAI) Brochure 1960 (TGAI) Bayer Report No. 75142, submitted with this application
61-2	Statement of Composition	41205710 44648201	3125 3125 11556		PER PER OWN	Brochure 1628 (TGAI) Brochure 1960 (TGAI) Bayer Report No. 75142, submitted with this application
61-3	Discussion of formation of impurities	41205710 44648201	3125 3125 11556		PER PER OWN	Brochure 1628 (TGAI) Brochure 1960 (TGAI) Bayer Report No. 75142, submitted with this application
62-1	Preliminary analysis	41205711 44648201	3125 3125 11556		PER PER OWN	Brochure 1629 (TGAI) Brochure 1960 (TGAI) Bayer Report No. 75142, submitted with this application

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07-03-00

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DATA MATRIX

Date June 30, 2000		EPA Reg No./File Symbol 11556-~~xxx~~ RGL	Page 2 of 11
Applicant's/Registrant's Name & Address	Bayer Corporation Agriculture Division, Animal Health P.O. Box 390 Shawnee Mission, KS 66201	Product Cutter® Ultra Insecticide Cattle Ear Tag	
Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
62-2	Certification of Limits	41205711 44648201	3125 3125 11556	PER PER OWN	Brochure 1629 (TGAI) Brochure 1960 (TGAI) Bayer Report No. 75142, submitted with this application
62-3	Analytical method for enforcement limits	41205711 44648201	3125 3125 11556	PER PER OWN	Brochure 1629 (TGAI) Brochure 1960 (TGAI) Bayer Report No. 75142, submitted with this application
63-1	Chemical and Physical Properties	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application
63-2	Appearance (Color)	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application
63-3	Physical State	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application

Form Approved OMB No. 2070-0060

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Applicant's/Registrant's Name & Address	Bayer Corporation Agriculture Division, Animal Health P.O. Box 390 Shawnee Mission, KS 66201		Product Cutter® Ultra Insecticide Cattle Ear Tag		
Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-4	Odor		11556	OWN	Bayer Report No. 75142, submitted with this application
63-5	Melting Point	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application
63-6	Boiling Point		11556	OWN	Bayer Report No. 75142, submitted with this application
63-7	Density, bulk-density, or specific gravity	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application
63-8	Solubility	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application
63-9	Vapor Pressure	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application

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DATA MATRIX

Date June 30, 2000			EPA Reg No./File Symbol 11556-~~xxx~~ RGR		Page 4 of 11
Applicant's/Registrant's Name & Address	Bayer Corporation Agriculture Division, Animal Health P.O. Box 390 Shawnee Mission, KS 66201		Product Cutter® Ultra Insecticide Cattle Ear Tag		
Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5					
Guideline Reference Number	**Guideline Study Name**	**MRID Number**	**Submitter**	**Status**	**Note**
63-10	Dissociation constant	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application
63-11	Octanol/water partition coefficient	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application
63-12	pH	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application
63-13	Stability	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application
63-14	Oxidizing or Reduction Potential	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application

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401 M Street, S.W.
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DATA MATRIX

Date June 30, 2000		EPA Reg No./File Symbol 11556 RGR	Page 5 of 11
Applicant's/Registrant's Name & Address	Bayer Corporation Agriculture Division, Animal Health P.O. Box 390 Shawnee Mission, KS 66201	Product Cutter® Ultra Insecticide Cattle Ear Tag	
Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-15	Flammability	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application
63-16	Explodability	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application
63-18	Viscosity	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application
63-19	Miscibility	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application
63-20	Corrosion characteristics	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application

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Date June 30, 2000		EPA Reg No./File Symbol 11556~~-xxxx~~ RGR	Page 6 of 11
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Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-21	Dielectric breakdown	41205712	3125 11556	PER OWN	Brochure 1630 (TGAI) Bayer Report No. 75142, submitted with this application
64-1	Samples				Samples available upon request
Section 158.340	TOXICOLOGY				
81-1	Acute oral toxicity, rat 3125-289 →	41244101 41244102 41244103 41244104	3125 3125 3125 3125	PER	Report No. 98349 (TGAI) Report No. 98351 (TGAI) Report No. 98350 (TGAI) Report No. 98588 (TGAI)
81-2	Acute dermal toxicity, rat ↘	41244105 41244106	3125 3125	PER	Report No. 97488 (TGAI) Report No. 98286 (TGAI)
81-3	Acute inhalation toxicity, rat 3125-389	41205701	3125	PER	Report No. 98469 (TGAI)
81-4	Primary eye irritation, rabbit 3125-389	41205702	3125	PER	Report No. 99151 (TGAI)
81-5	Primary dermal irritation, rabbit 3125-389	41205702	3125	PER	Report No. 99151 (TGAI)

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DATA MATRIX

Date June 30, 2000		EPA Reg No./File Symbol 11556-[redacted] RGR	Page 7 of 11
Applicant's/Registrant's Name & Address	Bayer Corporation Agriculture Division, Animal Health P.O. Box 390 Shawnee Mission, KS 66201	Product Cutter® Ultra Insecticide Cattle Ear Tag	
Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-6	Dermal sensitization, guinea pig	41244107	3125	PER	Report No. 97402 (TGAI)
81-7	neurotoxicity, Hen	00163040	3125	PER	93094 (TGAI)
82-1(a)	90 Day Subchronic - Rodent	00131523	3125	PER	Rprt No. 69921 (TGAI)
82-2	21-Day Repeated Dose Dermal Toxicity	00131527	3125	PER	Rprt. No. 69924 (TGAI)
82-4	21-Day Inhalation	00131528	3125	PER	Rprt. No. 69920 (TGAI)
82-5(b)	Subchronic Neurotoxicity Screening - Rat	44296001	3125	PER	Rprt. No. 107491 (β-cyfluthrin)
83-1(a)	Chronic Feeding Study - Rodent	00137303	3125	PER	Rprt No. 86032 (TGAI)
83-1(b)	Chronic Feeding Study - Non-rodent	00151358	3125	PER	Rprt No. 86031 (TGAI)

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Date June 30, 2000		EPA Reg No./File Symbol 11556-~~xxx~~ RGL	Page 8 of 11
Applicant's/Registrant's Name & Address	Bayer Corporation Agriculture Division, Animal Health P.O. Box 390 Shawnee Mission, KS 66201	Product Cutter® Ultra Insecticide Cattle Ear Tag	
Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-2(a)	Oncogenicity - Rat	00137303	3125	PER	Rprt No. 86032 (TGAI)
83-2(b)	Oncogenicity - Mouse	00137304	3125	PER	Rprt No. 86107 (TGAI)
83-3(a)	Developmental Toxicity - Rat	00157794	3125	PER	Rprt No. 86477 (TGAI)
83-3(b)	Developmental Toxicity - Rabbit	42675401	3125	PER	Rprt No. 103980 (TGAI)
83-4	Two Generation Reproduction	00131532	3125	PER	Rprt No. 85881 (TGAI)
84-2(a)	Gene mutation	41244110 41244112	3125 3125	PER	Rprt No. 95605 (TGAI) Rprt No. 97481 (TGAI)
84-2(b)	Structural Chromosomal Aberration	41244111 41205703	3125 3125	PER	Rprt No. 97415 (TGAI) Rprt No. 98361 (TGAI)

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DATA MATRIX

Date June 30, 2000		EPA Reg No./File Symbol 11556~~-xxx~~ RGR	Page 9 of 11
Applicant's/Registrant's Name & Address	Bayer Corporation Agriculture Division, Animal Health P.O. Box 390 Shawnee Mission, KS 66201	Product Cutter® Ultra Insecticide Cattle Ear Tag	
Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
84-4	Other Genotoxic Effects	41205704	3125	PER	Rprt No. 98585 (TGAI)
85-1	General Metabolism - Rat	00131517	3125	PER	Rprt No. 82349 (TGAI)
86-1	Domestic Animal Safety	41555704	11556	OWN	Report No. 74013
171-3	Directions for Use		11556	OWN	Label Draft submitted with this application
171-4(b)	Nature of Residue - Animal	MRID 137549 MRID 131506	3125 3125	PER	Miles Brochure No. 1223
171-4(d)	Analytical Method - Animal	MRID 4030502 MRID 137548	3125 3125	PER	Rprt No. 85883 Rprt No. 86232
171-4(e)	Storage Stability	43533703	3125	PER	Rprt No. 94303

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DATA MATRIX

Date June 30, 2000		EPA Reg No./File Symbol 11556-~~ooo~~ RGL	Page 10 of 11
Applicant's/Registrant's Name & Address	Bayer Corporation Agriculture Division, Animal Health P.O. Box 390 Shawnee Mission, KS 66201	Product Cutter® Ultra Insecticide Cattle Ear Tag	
Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-4(j)	Magnitude of Residue Meat/milk/poultry/egg	00131506 00137549 41001621 43533702 43533701 43803001 41555702 41555703	3125 3125 3125 3125 3125 3125 11556 11556	PER OWN OWN	Rprt No. 86045 and Rprt No. 86046, part of Brochure 1223 Rprt No. 98505 Rprt No. 106628 Rprt No. 106629 Rprt No. 106977 Rprt No. 74050 Rprt No. 74051
171-5	Reduction of Residue	FAP No. 1F3923 FAP No. 9F3731 FAP No. 4F3046	11556 3125 3125	OWN PER PER	Petition No. 1F3923 Petition No. 9F3731 Petition No. 4F3046
171-6	Proposed Tolerance	FAP No. 1F3923 FAP No. 9F3731 FAP No. 4F3046	11556 3125 3125	OWN PER PER	Petition No. 1F3923 Petition No. 9F3731 Petition No. 4F3046
171-7	Support for Tolerance	FAP No. 1F3923 FAP No. 9F3731 FAP No. 4F3046	11556 3125 3125	OWN PER PER	Petition No. 1F3923 Petition No. 9F3731 Petition No. 4F3046

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Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-13	Analytical Reference Standard				Available upon request

Signature F. Terry McNamara	F. Terry McNamara Manager, Preclinical Development	Date: 6/30/00

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Form Approved. OMB No. 2070-0060. Approval Expires 5-31-98.

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
Bayer Corporation Agriculture Division, Animal Health P.O. 390 Shawnee Mission, KS 66201-0390	11556-~~70EE~~ RGR
	Product Name Cutter Ultra Insecticide Cattle Ear Tag
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 6/30/2000

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

FCR 4545 (beta-cyfluthrin)

Piperonyl Butoxide

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ **(A) An accurate Confidential Statement of Formula** *(EPA FORM 8570-4)* **for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).**

OR

☐ **(B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.**

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Piperonyl Butoxide	[redacted]	[redacted]

Signature	Name and Title	Date
F. Terry McNamara	F. Terry McNamara, Mgr - Preclin Dev	6/30/2000

EPA Form 8570-27 (Rev. 8-95)

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Yellow - Applicant copy

★ U.S. GPO: 1995-386-830/20413

Product ingredient source information may be entitled to confidential treatment

N/F.T.

B

via Federal Express 06/30/00

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Document Processing Desk (APPL)
U.S. Environmental Protection Agency
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1921 Jefferson Davis Highway
Arlington, VA 22202

Attachments: Application for Pesticide Registration–
Cutter Ultra Cattle Insecticide Ear Tag (Reg. No. 11556-RGR)
Letter of Authorization from Bayer Crop Protection
Draft Label (Five Copies)
Transmittal Document with Bayer Report No. 75142 (Three Copies)
Confidential Statement of Formula (Two Copies)
Certification with Respect to Citation of Data
Formulator's Exemption Statement
Data Matrix
Data Matrix – Public Version

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06/30/00

Pages 206-213 - *Confidential Statements of Formula may be entitled to confidential treatment*